

# Exhibit 12

Page 1

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF NEW JERSEY  
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)

6 IN RE JOHNSON & JOHNSON ) MDL No. 16-2738

TALCUM POWDER PRODUCTS ) (MAS) (RLS)

7 MARKETING, SALES PRACTICES )

AND PRODUCT LIABILITY )

8 LITIGATION )

)

9 -----x

10  
11 V O L U M E I  
12

13 DEPOSITION OF CHERYL C. SAENZ, M.D.

14 LA JOLLA, CALIFORNIA

15 WEDNESDAY, JUNE 19, 2024

16 9:13 A.M.  
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21  
22

23 Job No.: 6753335

24 Pages: 1 - 307

25 Reported by: Leslie A. Todd, CSR No. 5129 and RPR

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2 the conference room at the:	2 EXAMINATION OF CHERYL C. SAENZ, M.D. PAGE
3	3 By Ms. O'Dell 9
4	4
5 GRANDE COLONIAL HOTEL	5
6 910 Prospect Street	6 E X H I B I T S
7 La Jolla, California 92037	7 (Attached to transcript)
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10 Cheryl Saenz, M.D. and Duces	10 Cheryl Saenz, M.D. and Duces
11	11 Tecum 9
12 Pursuant to notice, before Leslie Anne Todd,	12 No. 2 Amended Expert Report of Cheryl C.
13 California Certified Shorthand Reporter in and for	13 Saenz, M.D., May 21, 2024 19
14 the State of California, who officiated in	14 No. 3 Expert Report of Cheryl Christine
15 administering the oath to the witness.	15 Saenz, MD, for General Causation
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21 155 Seaport Boulevard	21 Hilary 128
22 Boston, Massachusetts 02210	22 No. 14 Article in Fertility and Sterility:
23 (617) 439-2000	23 Effects of risk factors for
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<p style="text-align: right;">Page 10</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. And when you have that in front of</p> <p>3 you, Doctor, I want to ask you a few questions</p> <p>4 about it.</p> <p>5 A. Thank you. I have it.</p> <p>6 Q. Oh, thank you.</p> <p>7 First, have you seen this document</p> <p>8 before?</p> <p>9 A. Yes.</p> <p>10 Q. And have you brought with you any</p> <p>11 materials in response to the document request at</p> <p>12 the end of the notice?</p> <p>13 MS. CURRY: I just want to put</p> <p>14 on the record that there were objections</p> <p>15 filed in response to the notice of</p> <p>16 deposition as well as some documents</p> <p>17 that have been produced on behalf of</p> <p>18 Dr. Saenz.</p> <p>19 BY MS. O'DELL:</p> <p>20 Q. Okay. Are there any additional</p> <p>21 documents in addition to the ones that were</p> <p>22 produced to us I think two or three days ago that</p> <p>23 you brought to the deposition that you've not yet</p> <p>24 made available to plaintiffs?</p>	<p style="text-align: right;">Page 12</p> <p>1 apologize.</p> <p>2 MS. O'DELL: No, no problem.</p> <p>3 BY MS. O'DELL:</p> <p>4 Q. So, Dr. Saenz, in front of you, you</p> <p>5 have your reports, hard copies of your reports.</p> <p>6 Do you have any copies of scientific articles or</p> <p>7 scientific literature?</p> <p>8 A. No.</p> <p>9 Q. Okay. I want to just, for</p> <p>10 efficiency sake, go through the notice and just</p> <p>11 ask you a few questions, and in particular, if I</p> <p>12 could ask you to turn to page 8.</p> <p>13 A. Okay.</p> <p>14 Q. To Request No. 14.</p> <p>15 A. Okay.</p> <p>16 Q. And we asked you for documents that</p> <p>17 related to communications with certain</p> <p>18 organizations, and I want to ask you if you have</p> <p>19 any documents related to communications you've</p> <p>20 had with these organizations: The Food and Drug</p> <p>21 Administration?</p> <p>22 A. No.</p> <p>23 Q. Have you had any communications</p> <p>24 with them where they were documented in an e-mail</p>
<p style="text-align: right;">Page 11</p> <p>1 A. No. I have copies of my reports,</p> <p>2 but I do believe that those were all made</p> <p>3 available to you previously.</p> <p>4 Q. Yes, they were.</p> <p>5 Is there anything else that you</p> <p>6 have in front of you this morning in paper copy</p> <p>7 other than your reports?</p> <p>8 A. No.</p> <p>9 MS. CURRY: And --</p> <p>10 BY MS. O'DELL:</p> <p>11 Q. So no --</p> <p>12 MS. CURRY: Oh, I'm so sorry to</p> <p>13 interrupt you. I just wanted to make a</p> <p>14 note. I noticed this morning that on</p> <p>15 the materials reviewed and considered</p> <p>16 list, inadvertently I did not put the</p> <p>17 newest amended reports of Dr. Daniel</p> <p>18 Clarke-Pearson and Dr. Wolf that were</p> <p>19 produced May 28th, 2024. However,</p> <p>20 Dr. Saenz has in fact reviewed those, so</p> <p>21 we can update that and provide it to</p> <p>22 you, but everything else you should have</p> <p>23 in your possession. That was just an</p> <p>24 inadvertent disclosure on my part, so I</p>	<p style="text-align: right;">Page 13</p> <p>1 or any other writing?</p> <p>2 A. No.</p> <p>3 Q. Have you ever had any</p> <p>4 communications of any type with Health Canada?</p> <p>5 A. No.</p> <p>6 Q. Have you ever had any</p> <p>7 communications regarding talc with leadership of</p> <p>8 the Society of Gynecologic Oncology?</p> <p>9 MS. CURRY: Object to the form.</p> <p>10 THE WITNESS: No.</p> <p>11 BY MS. O'DELL:</p> <p>12 Q. And I want to try to address the</p> <p>13 objection. In regard to the Society of</p> <p>14 Gynecologic Oncology, have you discussed talc</p> <p>15 with any officer of the Society of Gynecologic</p> <p>16 Oncology at any point during the time you've been</p> <p>17 an expert in this litigation?</p> <p>18 A. No.</p> <p>19 Q. Have you had any conversations or</p> <p>20 communications with an officer or employee of the</p> <p>21 American College of Obstetrics and Gynecology</p> <p>22 regarding talc and ovarian cancer?</p> <p>23 MS. CURRY: Object to the form.</p> <p>24 THE WITNESS: No.</p>

<p style="text-align: right;">Page 14</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. Have you had any discussions with</p> <p>3 an employee or a representative of the American</p> <p>4 Society of Clinical Oncology about talc and</p> <p>5 ovarian cancer?</p> <p>6 A. No.</p> <p>7 Q. Have you had any communications,</p> <p>8 conversations, oral or in writing, to the</p> <p>9 International Agency for Research on Cancer</p> <p>10 regarding talc and ovarian cancer?</p> <p>11 A. No.</p> <p>12 Q. I have the same question about the</p> <p>13 American Cancer Society. Have you had any</p> <p>14 communications, orally or in writing, with the</p> <p>15 American Cancer Society or a representative of</p> <p>16 the American Cancer Society regarding talc and</p> <p>17 ovarian cancer?</p> <p>18 A. No.</p> <p>19 Q. Are you involved with the American</p> <p>20 Cancer Society as a volunteer or in any other</p> <p>21 capacity?</p> <p>22 A. Presently?</p> <p>23 Q. Yes.</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 16</p> <p>1 what I'm asking for. Thank you.</p> <p>2 Have you ever had any discussions</p> <p>3 with the -- sort of the national office of the</p> <p>4 American Cancer Society, any of their employees</p> <p>5 or representatives?</p> <p>6 A. No.</p> <p>7 Q. Have you ever interacted or</p> <p>8 communicated, either in writing or orally, with</p> <p>9 the Centers for Disease Control regarding talc</p> <p>10 and ovarian cancer?</p> <p>11 A. No.</p> <p>12 Q. In regard to the National</p> <p>13 Comprehensive Cancer Network, my first question</p> <p>14 is, have you ever been a part or affiliated with</p> <p>15 the National Comprehensive Cancer Network?</p> <p>16 A. Not on a committee level that I</p> <p>17 would be responsible for a publication. However,</p> <p>18 certain other people that are attending at the</p> <p>19 Moores Cancer Center are on those committees, and</p> <p>20 at various times when there's new guidelines</p> <p>21 coming out, in particular for endometrial and</p> <p>22 cervical cancer treatment, and just the breadth</p> <p>23 and depth of what they publish, I've been asked</p> <p>24 to review those new changes prior to them being</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. Have you been in the past?</p> <p>2 A. Yes.</p> <p>3 Q. In what capacity?</p> <p>4 A. When I was chair of the cancer</p> <p>5 committee at the Moores UCSD Cancer Center, there</p> <p>6 was a representative of the local branch of the</p> <p>7 American Cancer Society that participated in our</p> <p>8 meetings. And if there were events sponsored by</p> <p>9 the American Cancer Society here in San Diego, we</p> <p>10 would often participate in those events.</p> <p>11 Q. During what time period did you</p> <p>12 have -- engage with local members of the American</p> <p>13 Cancer Society there in San Diego?</p> <p>14 A. I remember I became chair of that</p> <p>15 committee when I was pregnant with my oldest</p> <p>16 child, who's now 22, so that would have been</p> <p>17 starting in 2002. And I believe I was chair of</p> <p>18 that committee for 12 or 13 years. So that would</p> <p>19 take us up somewhere between 2014 to 2015.</p> <p>20 My CV, Ms. O'Dell, would have the</p> <p>21 actual dates that I was chair of that committee.</p> <p>22 I'm sorry, I'm trying to give you my best</p> <p>23 recollection, but...</p> <p>24 Q. That's -- that's fair, and that's</p>	<p style="text-align: right;">Page 17</p> <p>1 made public.</p> <p>2 Q. Okay. Have you ever reviewed any</p> <p>3 information regarding ovarian cancer for the</p> <p>4 National Comprehensive Cancer Network?</p> <p>5 A. No.</p> <p>6 Q. Have you ever had any</p> <p>7 communication -- and if you don't mind, I'll just</p> <p>8 abbreviate it because it's a long name -- NCCN,</p> <p>9 have you had any communications with NCCN</p> <p>10 regarding ovarian cancer and talcum powder?</p> <p>11 A. No.</p> <p>12 Q. And lastly, I want to ask you about</p> <p>13 the Ovarian Cancer Research Alliance, often</p> <p>14 referred to as OCRA, have you had any involvement</p> <p>15 with OCRA as a volunteer or a member of a</p> <p>16 committee?</p> <p>17 A. No.</p> <p>18 Q. Have you had any communications in</p> <p>19 writing or orally with either a member or an</p> <p>20 affiliate of OCRA regarding ovarian cancer and</p> <p>21 talcum powder?</p> <p>22 A. No.</p> <p>23 Q. Do you have colleagues there at</p> <p>24 University of San Diego that are involved in OCRA</p>

<p style="text-align: right;">Page 18</p> <p>1 and are -- let me just stop there, are involved  2 with OCRA?  3 MS. CURRY: Object to the form.  4 THE WITNESS: I don't know.  5 BY MS. O'DELL:  6 Q. Have you discussed with any of your  7 colleagues ovarian cancer and research related to  8 the work of OCRA?  9 MS. CURRY: Object to the form.  10 THE WITNESS: In -- with respect  11 to talc and ovarian cancer or just in  12 general?  13 BY MS. O'DELL:  14 Q. I will limit it to talc and ovarian  15 cancer.  16 A. No, I have not had any such  17 conversations.  18 Q. Okay. Thank you.  19 Dr. Saenz, you can put that away if  20 you'd like.  21 Next I'd like to mark, and we'll be  22 referring to this throughout the day, as  23 Exhibit 2, and that's your expert report, your  24 general expert report.</p>	<p style="text-align: right;">Page 20</p> <p>1 THE WITNESS: Oh, it is pink.  2 BY MS. O'DELL:  3 Q. I wasn't overstating it. It's very  4 pink.  5 A. Nope.  6 Q. So, first, let me step back for a  7 moment.  8 Dr. Saenz --  9 MS. O'DELL: And thank you,  10 Paula, for that.  11 BY MS. O'DELL:  12 Q. Dr. Saenz, Exhibit 2, is that an  13 accurate and -- copy of your expert report in the  14 MDL dated May 21st, 2024?  15 A. I mean, I haven't had a chance to  16 look through it, but the number of pages looks  17 about correct. So -- I mean, I have no reason to  18 doubt you, but I'm not going to sit here and read  19 it to verify that, but it looks approximately  20 like -- I mean it --  21 Q. Your answer was better than my  22 question. I just wanted to get it identified for  23 the record.  24 A. Yes.</p>
<p style="text-align: right;">Page 19</p> <p>1 (Exhibit No. 2 was marked for  2 identification.)  3 BY MS. O'DELL:  4 Q. And so we will get that in front of  5 you.  6 MS. O'DELL: Thank you, Paula.  7 THE WITNESS: Thank you.  8 BY MS. O'DELL:  9 Q. And then also while Paula is giving  10 you the actual report, I'll ask if we can also  11 mark as Exhibit 3 a comparator document.  12 (Exhibit No. 3 was marked for  13 identification.)  14 BY MS. O'DELL:  15 Q. And let me get that in front of  16 you, and I'll explain to you what it is,  17 Dr. Saenz. It's the comparison of the report  18 from 2019 to her general report in 2024.  19 MS. O'DELL: And let's see,  20 Paula, I think it's identified as  21 comparison -- the Saenz expert report  22 comparison. It should be at the front.  23 It looks very pink if that helps.  24 MS. BROWN: Yep.</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. And then -- and so we'll be  2 referring to that throughout the day.  3 And then what's been marked as  4 Exhibit 3, I'll represent to you, Dr. Saenz, is  5 an electronic comparison of your report that was  6 disclosed in the MDL in February of 2019 to the  7 general report that you disclosed to the MDL on  8 May 21st, 2024. And we may have an opportunity  9 to refer to that during the day, but this is  10 just -- will help us know what you disclosed in  11 2019 versus the report that you disclosed in  12 2024.  13 Is that fair?  14 A. Yes.  15 Q. Okay. Going back to your report  16 itself, your current 2024 report that's been  17 marked as Exhibit No. 2, I'd like for you to  18 turn, if you will, please, to Exhibit A, which is  19 on page 60, and it's your curriculum vitae.  20 A. Okay.  21 Q. And we've had opportunity to talk  22 before, so I'm not going to ask you a lot of  23 questions about it, but I do want to know, is  24 this an up-to-date curriculum vitae?</p>



<p style="text-align: right;">Page 22</p> <p>1 MS. CURRY: And just for the</p> <p>2 record, we did produce in response to</p> <p>3 the notice of deposition a more updated</p> <p>4 version of the CV, which should be</p> <p>5 swapped out with this Exhibit A.</p> <p>6 MS. O'DELL: Okay. Okay. I</p> <p>7 will pull that up and we will mark that</p> <p>8 later in the deposition. But it will</p> <p>9 take me a minute to pull it up, so I</p> <p>10 won't -- I'll do that at the break.</p> <p>11 BY MS. O'DELL:</p> <p>12 Q. Dr. Saenz, what are the</p> <p>13 differences, if you know, between this CV that's</p> <p>14 dated November 2023 and the updated CV that was</p> <p>15 produced within the last few days?</p> <p>16 A. There are some updated publications</p> <p>17 I believe I have detailed in there -- and I don't</p> <p>18 know if it's in this one, but I believe I have</p> <p>19 detailed in there an administrative position that</p> <p>20 I now hold at the hospital.</p> <p>21 I believe that I also have in there</p> <p>22 a description of an engagement that I have with</p> <p>23 CMS to be a reviewer of appeals for healthcare,</p> <p>24 that patients get denied, and then they're</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. And, Dr. Saenz, this CV is dated</p> <p>2 June of 2024, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. Okay. And let me ask you to go</p> <p>5 back just for a moment. You mentioned that you</p> <p>6 have a new administrative role there at the</p> <p>7 University of San Diego. What is that role?</p> <p>8 A. So on page 3 under "Administrative</p> <p>9 Appointments," it lists that I am the medical</p> <p>10 director of Referral Management.</p> <p>11 Q. Okay. Give me just a moment to get</p> <p>12 there.</p> <p>13 A. Of course.</p> <p>14 Q. What is Referral Management?</p> <p>15 A. One of the initiatives that the</p> <p>16 medical group has put forth as a primary area of</p> <p>17 focus is improving patient access to subspecialty</p> <p>18 care and care at UCSD Medical Group in general.</p> <p>19 So in particular, my responsibility</p> <p>20 is to focus on getting new patient referrals in</p> <p>21 to see the subspecialists in a timely manner with</p> <p>22 the appropriate prior workup and documents. The</p> <p>23 initiative is actually called RP2, which stands</p> <p>24 for right patient, right provider. And I am the</p>
<p style="text-align: right;">Page 23</p> <p>1 appealing that denial with their insurer. It's</p> <p>2 through the State of California.</p> <p>3 And then I think there's also a</p> <p>4 detail of part of a research grant that I am on</p> <p>5 now that has been updated.</p> <p>6 Q. So let me just put in the chat</p> <p>7 quickly because I was able to find it pretty</p> <p>8 easily. So I have put in the chat, if you need</p> <p>9 it, a copy of the June 2024 CV that you</p> <p>10 mentioned. And I'm going to put it on the</p> <p>11 screen.</p> <p>12 MS. CURRY: Leigh, I actually</p> <p>13 have a hard copy. Is there any</p> <p>14 objection to me providing that to</p> <p>15 Dr. Saenz just for ease of reference?</p> <p>16 MS. O'DELL: Not at all.</p> <p>17 THE WITNESS: Thank you.</p> <p>18 MS. O'DELL: That's fine.</p> <p>19 So for the new CV, Leslie, I</p> <p>20 would like to mark that as -- I believe</p> <p>21 we're at Exhibit 4.</p> <p>22 (Exhibit No. 4 was marked for</p> <p>23 identification.)</p> <p>24 BY MS. O'DELL:</p>	<p style="text-align: right;">Page 25</p> <p>1 medical doctor -- medical director for that</p> <p>2 project, and my team consists of various people</p> <p>3 from IT, information services, patient advocacy,</p> <p>4 things such as that.</p> <p>5 Q. So what percentage of your</p> <p>6 professional time does this new position</p> <p>7 encompass?</p> <p>8 A. Ten percent. I'm sorry, 20</p> <p>9 percent. It's one day a week, theoretically.</p> <p>10 Eight hours a week, so that's 20 percent. But no</p> <p>11 doctor works a 40-hour workweek, so...</p> <p>12 Q. What percentage of your time</p> <p>13 currently is devoted -- your professional time is</p> <p>14 devoted to serving as medical director of the</p> <p>15 family center for early detection of ovarian</p> <p>16 cancer?</p> <p>17 A. That's actually more of an honorary</p> <p>18 title than it is actually a time allotment of</p> <p>19 work that needs to be done.</p> <p>20 Q. Okay.</p> <p>21 A. I do not receive any compensation</p> <p>22 for that position.</p> <p>23 Q. And what percentage of your time</p> <p>24 presently is devoted to the clinical care of</p>



<p style="text-align: right;">Page 26</p> <p>1 patients?</p> <p>2 A. I am still clinically active five</p> <p>3 days a week unless I'm on call, in which case I'm</p> <p>4 on for seven days in a row. So I'm in the</p> <p>5 clinics three days a week, I have OR five days a</p> <p>6 month, and so I'm still clinically active five</p> <p>7 days a week.</p> <p>8 We are actually recruiting for a</p> <p>9 new partner because we're overly busy and trying</p> <p>10 to offload some of the clinical work, as some of</p> <p>11 us take on more administrative positions.</p> <p>12 Q. You mentioned that you have some</p> <p>13 new publications that have been added to your</p> <p>14 updated CV. Are any of those publications -- do</p> <p>15 any of those publications involve ovarian cancer?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. Would you tell me what page?</p> <p>18 A. Page 12, which is the page with</p> <p>19 abstracts. And the abstracts are listed with the</p> <p>20 most recent first.</p> <p>21 So the second abstract involves all</p> <p>22 gynecologic cancers. The third abstract and the</p> <p>23 fourth abstract are bench work abstracts</p> <p>24 involving ovarian cancer. And the -- I think</p>	<p style="text-align: right;">Page 28</p> <p>1 So I was responsible for the write-up of that</p> <p>2 paper -- part of the write-up of that paper.</p> <p>3 And then --</p> <p>4 Q. Are you talking about, Dr. Saenz,</p> <p>5 the -- the May 2024 publication at the bottom of</p> <p>6 page 17?</p> <p>7 A. Yes. Yes.</p> <p>8 Q. Okay.</p> <p>9 A. And I think that's all that's new</p> <p>10 for publications.</p> <p>11 Q. Okay. Since 2019, have you written</p> <p>12 any scientific publications, be they full</p> <p>13 manuscripts, abstracts, posters, that involve</p> <p>14 talc and ovarian cancer?</p> <p>15 A. No.</p> <p>16 Q. Are you currently working on any</p> <p>17 research regarding talc and ovarian cancer?</p> <p>18 A. Can you better define "research"</p> <p>19 for me?</p> <p>20 Q. Yes. Any -- any activities that</p> <p>21 evaluate the scientific data relating to the</p> <p>22 genital use of talc and ovarian cancer that you</p> <p>23 plan to publish in the literature.</p> <p>24 A. No.</p>
<p style="text-align: right;">Page 27</p> <p>1 that's it for the abstracts that aren't new and</p> <p>2 involve ovarian cancer. And --</p> <p>3 Q. Before you turn --</p> <p>4 A. Yes.</p> <p>5 Q. -- let me just ask a question about</p> <p>6 this bench work. Were you actively involved in</p> <p>7 the bench work that's reported in these</p> <p>8 abstracts?</p> <p>9 A. I was --</p> <p>10 MS. CURRY: Object to the form.</p> <p>11 THE WITNESS: I was more of a</p> <p>12 content reviewer, an advisor for the</p> <p>13 writing up of the publication. I did</p> <p>14 not actually stand at the benchtop</p> <p>15 myself and conduct the science.</p> <p>16 BY MS. O'DELL:</p> <p>17 Q. Okay. Thank you.</p> <p>18 A. Of course.</p> <p>19 May I turn now?</p> <p>20 Q. Yes, please.</p> <p>21 A. On page 17, the first paper is a</p> <p>22 publication that involved patients that had</p> <p>23 concurrent endometrial and ovarian cancers, and I</p> <p>24 was a content contributor to that publication.</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. Any -- same question really, but in</p> <p>2 regard to abstracts or a poster that would be</p> <p>3 presented at a professional meeting.</p> <p>4 A. No.</p> <p>5 Q. And we may have touched on this,</p> <p>6 Dr. Saenz, so if we did, I apologize, but I just</p> <p>7 want to make sure I'm not missing something.</p> <p>8 Since 2019 have you served as a</p> <p>9 primary investigator on any research or studies</p> <p>10 that relate to ovarian cancer?</p> <p>11 A. As a PI specifically, no.</p> <p>12 Q. Since 2019 have you published any</p> <p>13 research regarding the -- let me just expand</p> <p>14 that -- any research, whether you're an author on</p> <p>15 the abstract or publication, have you published</p> <p>16 any research regarding modifiable risk factors</p> <p>17 for ovarian cancer?</p> <p>18 A. No.</p> <p>19 Q. Same question but for risk factors</p> <p>20 in general, not just limited to modifiable risk</p> <p>21 factors.</p> <p>22 A. No.</p> <p>23 Q. You also mentioned in regard to</p> <p>24 your CV that there was a new grant that you</p>

<p style="text-align: right;">Page 30</p> <p>1 recently received, and that was one of the</p> <p>2 updates. Would you please direct me to the grant</p> <p>3 you're referring to.</p> <p>4 A. Yes. On page 9, at the bottom</p> <p>5 under Research Support is Current Research</p> <p>6 Support, and the PI on that grant is Rebecca</p> <p>7 Rakow-Penner.</p> <p>8 Q. And what's the purpose or the</p> <p>9 objective of the study?</p> <p>10 A. The objective of the study is to</p> <p>11 utilize MRIs to evaluate patients with cervical</p> <p>12 cancer that are being treated with radiation to</p> <p>13 try and determine if they're responding</p> <p>14 appropriately or not with the MRI.</p> <p>15 Q. All right. Thank you.</p> <p>16 Dr. Saenz, any other changes or</p> <p>17 updates in your curriculum vitae that we haven't</p> <p>18 touched on?</p> <p>19 A. I think I mentioned that I'm</p> <p>20 involved with reviewing appeals of patients when</p> <p>21 their healthcare has denied coverage for certain</p> <p>22 interventions or certain medical care. I don't</p> <p>23 honestly know where that is. I'm not seeing it</p> <p>24 in here. I thought it was in here.</p>	<p style="text-align: right;">Page 32</p> <p>1 What methodology did you use to</p> <p>2 update your expert report?</p> <p>3 A. So from the 2019 report, which I</p> <p>4 had, I went ahead and searched the literature for</p> <p>5 any new publications on the topic of -- on the</p> <p>6 topics of talc and ovarian cancer development,</p> <p>7 risk factors for ovarian cancer. I searched for</p> <p>8 original publications. I searched for society</p> <p>9 statements. I did pretty broad web searches for</p> <p>10 keywords such as ovarian cancer, inflammation,</p> <p>11 talc, risk factors, and then read the documents</p> <p>12 that I found, incorporated them into my report.</p> <p>13 I read through the updated reports</p> <p>14 of Dr. Clarke-Pearson and Dr. Judith Wolf, and</p> <p>15 also read their depositions. Yeah, I think that</p> <p>16 was the methodology that I used.</p> <p>17 Q. Did you typically use the same</p> <p>18 methodology for your 2024 report that you used</p> <p>19 for your 2019 report?</p> <p>20 A. Essentially.</p> <p>21 Q. And if I recall, in your 2019</p> <p>22 report you did not include a Bradford Hill</p> <p>23 analysis, and that's true also of your 2024</p> <p>24 report, correct?</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. And who employs you to do that</p> <p>2 work?</p> <p>3 A. It's contracted by CMS through an</p> <p>4 independent organization called Maximus, which is</p> <p>5 the group that CMS contracts to objectively</p> <p>6 review those appeals.</p> <p>7 Ah, I'm sorry, it's on page 6,</p> <p>8 Leigh.</p> <p>9 Q. All right. Thank you.</p> <p>10 A. Under Honors and Activities. And</p> <p>11 it's the first one.</p> <p>12 Q. I see that. Okay. Thank you.</p> <p>13 And how much -- I see you started</p> <p>14 that position in April of 2022.</p> <p>15 A. I did the training in April of</p> <p>16 2022, but I did not actually review a case until,</p> <p>17 I believe, late 2023.</p> <p>18 Q. Okay. And how often are you</p> <p>19 involved in that work?</p> <p>20 A. Maybe three times a year.</p> <p>21 Q. Okay. Thank you.</p> <p>22 Dr. Saenz, I want to talk with you</p> <p>23 about your revised and amended report that we've</p> <p>24 marked as Exhibit 2.</p>	<p style="text-align: right;">Page 33</p> <p>1 MS. CURRY: Object to the form,</p> <p>2 misstates the facts.</p> <p>3 THE WITNESS: I -- I don't think</p> <p>4 that's accurate. I do believe that the</p> <p>5 analysis that I did back in 2019 as well</p> <p>6 as in 2024 follows the same conceptual</p> <p>7 formatting of a Bradford Hill analysis,</p> <p>8 looking at the literature and the data</p> <p>9 that's available, and evaluating those</p> <p>10 things by certain criteria, such as</p> <p>11 strength of association, biologic</p> <p>12 gradients, such as consistency in the</p> <p>13 literature, such as biologic</p> <p>14 plausibility. And I did actually put</p> <p>15 all of that forth in the 2019 report and</p> <p>16 again in the 2024 report.</p> <p>17 BY MS. O'DELL:</p> <p>18 Q. Okay. Is there -- can you turn me</p> <p>19 to in your report where you have a Bradford Hill</p> <p>20 analysis?</p> <p>21 A. So I do actually talk about the</p> <p>22 elements of a Bradford Hill analysis in my report</p> <p>23 and talk about how I examined the literature</p> <p>24 using those criteria that we just covered. I</p>

<p style="text-align: right;">Page 34</p> <p>1 don't have a word search function here, but I</p> <p>2 also do specifically mention Bradford Hill in the</p> <p>3 2024 report.</p> <p>4 Q. Can you point me to --</p> <p>5 A. On page 18 -- I'm sorry, page 18.</p> <p>6 Q. Okay. All right.</p> <p>7 A. The second paragraph. The second</p> <p>8 sentence.</p> <p>9 Would you like me to read it or are</p> <p>10 you reading it?</p> <p>11 Q. I'm reading it here. Are you</p> <p>12 talking about the sentence that begins that</p> <p>13 "Based upon my expertise"?</p> <p>14 A. Yes.</p> <p>15 Q. And that paragraph, is that your</p> <p>16 discussion of Bradford Hill's tenets?</p> <p>17 MS. CURRY: Object to the form.</p> <p>18 THE WITNESS: No, that's my</p> <p>19 discussion of the methodology that I</p> <p>20 used to evaluate the literature, and</p> <p>21 that I actually followed the criteria of</p> <p>22 Bradford Hill.</p> <p>23 BY MS. O'DELL:</p> <p>24 Q. Well, I -- okay. So I don't forget</p>	<p style="text-align: right;">Page 36</p> <p>1 be your work from 2019 and work that you've done</p> <p>2 since 2019 on either the MDL generally or the</p> <p>3 four other cases that you provided an opinion.</p> <p>4 MS. CURRY: And, Leigh, just so</p> <p>5 the record is clear, we actually wound</p> <p>6 up producing all of the invoices that</p> <p>7 relate to the MDL, and including work</p> <p>8 that was performed prior to 2019, just</p> <p>9 so that you had them all in one subset.</p> <p>10 MS. O'DELL: Okay. Thank you</p> <p>11 for that.</p> <p>12 BY MS. O'DELL:</p> <p>13 Q. So we've marked these as Exhibit</p> <p>14 No. 5. It's just a composite exhibit, Dr. Saenz.</p> <p>15 Do you recognize these documents?</p> <p>16 A. Yes.</p> <p>17 Q. And I want to try to go through and</p> <p>18 essentially understand the work that you were</p> <p>19 doing and also get a sense of what work you've</p> <p>20 done that you've not yet invoiced for.</p> <p>21 So, first, you should have at</p> <p>22 the -- on the top an invoice from March 6, 2019.</p> <p>23 Is that how you have them there?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 35</p> <p>1 it, Dr. Saenz, we had -- I'm going to come back</p> <p>2 to Bradford Hill later, but -- that will be a</p> <p>3 longer discussion.</p> <p>4 So I don't forget this part, let</p> <p>5 me ask Paula, if she will, to hand you a</p> <p>6 group of exhibits -- excuse me, invoices</p> <p>7 that we're going to mark as Exhibit 5.</p> <p>8 (Exhibit No. 5 was marked for</p> <p>9 identification.)</p> <p>10 BY MS. O'DELL:</p> <p>11 Q. And it's all the invoices that</p> <p>12 we've been provided to date for your work in the</p> <p>13 MDL.</p> <p>14 MS. CURRY: Leigh, is it just</p> <p>15 for the -- does it also include the</p> <p>16 individual invoices for the</p> <p>17 case-specific work on the four cases</p> <p>18 that she's here about today?</p> <p>19 MS. O'DELL: Yes.</p> <p>20 MS. CURRY: Okay.</p> <p>21 MS. O'DELL: Yes, it does.</p> <p>22 BY MS. O'DELL:</p> <p>23 Q. It includes -- and I'll ask you,</p> <p>24 Dr. Saenz, but it appears to include what would</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. And an invoice that totals</p> <p>2 \$100,500?</p> <p>3 A. Correct.</p> <p>4 Q. And this was for work in the MDL</p> <p>5 prior to the Dalbert hearing in 2019, correct?</p> <p>6 A. Correct.</p> <p>7 Q. And then there is a April 16th,</p> <p>8 2019 invoice totaling 43,215; is that correct?</p> <p>9 A. No, it's actually April 6th.</p> <p>10 Q. What did I say?</p> <p>11 A. April 16.</p> <p>12 Q. Oh, sorry. I apologize. April 6,</p> <p>13 2019.</p> <p>14 A. Correct.</p> <p>15 Q. And it's for \$43,215; is that</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. And then there's a September 30th,</p> <p>19 2019 invoice totaling \$78,502.60?</p> <p>20 A. Correct.</p> <p>21 Q. And then there are a series of four</p> <p>22 invoices, all dated on April 25th, 2022, and they</p> <p>23 are first for the Converse case in the amount of</p> <p>24 \$36,187.50; is that correct?</p>

<p style="text-align: right;">Page 38</p> <p>1 A. No, you said April 25th, and it's</p> <p>2 actually February 25th.</p> <p>3 Q. Well, that's a problem. In my</p> <p>4 mind, I thought February and out of my mouth came</p> <p>5 April. So I don't know if you ever had that</p> <p>6 experience before, but I did actually believe I</p> <p>7 was saying February.</p> <p>8 So February 25th, 2022. Do I have</p> <p>9 that correct?</p> <p>10 A. Yes, ma'am.</p> <p>11 Q. Okay. And so -- and that amount</p> <p>12 was for 36,000 -- excuse me, \$36,187.50, and that</p> <p>13 was for the Converse case.</p> <p>14 A. Yes, ma'am.</p> <p>15 Q. Correct?</p> <p>16 A. Correct.</p> <p>17 Q. Is that year on the invoice</p> <p>18 correct?</p> <p>19 A. Is that what?</p> <p>20 Q. Is the year correct, 2022?</p> <p>21 A. Yes.</p> <p>22 Q. And so you did this work during the</p> <p>23 pendency of the LTL bankruptcy, correct?</p> <p>24 MS. CURRY: Object to the form.</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. Approximately how many hours have</p> <p>2 you devoted to work for the MDL or for an MDL</p> <p>3 individual bellwether case since February of</p> <p>4 2022?</p> <p>5 MS. CURRY: Object to the form.</p> <p>6 THE WITNESS: It's a pure</p> <p>7 estimate. I have not produced any</p> <p>8 invoices or tallied any hours. I think</p> <p>9 I probably spent somewhere between 60 to</p> <p>10 70 hours in total.</p> <p>11 BY MS. O'DELL:</p> <p>12 Q. And that 60 to 70 hours would be</p> <p>13 for purposes of updating your general expert</p> <p>14 report and the work you described previously.</p> <p>15 True?</p> <p>16 A. Yes.</p> <p>17 Q. Reviewing medical records or other</p> <p>18 materials for the individual plaintiffs and</p> <p>19 writing your expert reports in those individual</p> <p>20 cases, correct?</p> <p>21 A. Well, there were -- I had reports</p> <p>22 written when I invoiced back in 2022 for each of</p> <p>23 these cases. So the reports were updated by me</p> <p>24 recently, not written de novo.</p>
<p style="text-align: right;">Page 39</p> <p>1 THE WITNESS: I did this work at</p> <p>2 the end of 2021 and completed it by</p> <p>3 February 25th, 2022. I don't know</p> <p>4 exactly how that correlates to what</p> <p>5 you're referencing, but that is the time</p> <p>6 frame that I did that work.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. Okay. And there's an invoice for</p> <p>9 the Rausa case, same date, for \$22,800, correct?</p> <p>10 A. Correct.</p> <p>11 Q. And another invoice, a third</p> <p>12 invoice dated February 25th, 2022, for \$35,812.50</p> <p>13 for the Judkins case, correct?</p> <p>14 A. Correct.</p> <p>15 Q. And a fourth invoice for the</p> <p>16 Newsome case, same date, \$26,812.50. Is that</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. And, Dr. Saenz, have you issued any</p> <p>20 invoices since February of 2022?</p> <p>21 A. In this matter?</p> <p>22 Q. Correct, or any of the underlying</p> <p>23 bellwether cases.</p> <p>24 A. No, I have not.</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. And was your rate for the work</p> <p>2 you've done since 2022, the 60 to 70 hours, is at</p> <p>3 a rate of \$750 an hour?</p> <p>4 A. Yes.</p> <p>5 Q. And does that 60 to 70 hours</p> <p>6 include preparation for your deposition today?</p> <p>7 A. Yes.</p> <p>8 Q. How many hours approximately did</p> <p>9 you spend either on your own preparing or with</p> <p>10 counsel to prepare for today's deposition?</p> <p>11 A. For today specifically?</p> <p>12 Q. Yes.</p> <p>13 A. Maybe five or six total.</p> <p>14 Q. Dr. Saenz, I want to ask you to set</p> <p>15 that aside for a moment.</p> <p>16 I want to mark one more exhibit</p> <p>17 along these lines, and that is exhibit -- it's</p> <p>18 going to be Exhibit 6, and it's your testimony</p> <p>19 list that you provided -- or your counsel</p> <p>20 provided in conjunction with your expert report</p> <p>21 that was provided to us in May of 2024.</p> <p>22 (Exhibit No. 6 was marked for</p> <p>23 identification.)</p> <p>24 BY MS. O'DELL:</p>

<p style="text-align: right;">Page 42</p> <p>1 Q. And is this an accurate listing of</p> <p>2 your prior testimony in the talc litigation?</p> <p>3 MS. CURRY: Object to the form.</p> <p>4 THE WITNESS: Well, since 2021,</p> <p>5 yes.</p> <p>6 BY MS. O'DELL:</p> <p>7 Q. And let me ask you, and maybe I'm</p> <p>8 mistaken, I was under the impression you</p> <p>9 testified in the Giese case in St. Louis in 2021.</p> <p>10 A. Was that the year it was? I'm</p> <p>11 sorry, I guess -- is that not the same as the</p> <p>12 Forrest, et al.? Oh, those -- I apologize, I do</p> <p>13 this every time you question me, Leigh. I get</p> <p>14 mixed up, because Forrest was initially a large</p> <p>15 conglomerate of cases and then they get pulled</p> <p>16 out.</p> <p>17 And so you are correct, Giese, I</p> <p>18 testified in, and that ended up being separate</p> <p>19 from the individual Forrest case, you are</p> <p>20 correct. I do that every time. I'm sorry.</p> <p>21 Q. And you also testified -- I</p> <p>22 apologize, I didn't mean to talk over you.</p> <p>23 So in addition to these cases -- I</p> <p>24 just want to make sure that I have a good</p>	<p style="text-align: right;">Page 44</p> <p>1 you've testified in?</p> <p>2 A. Regardless of the time --</p> <p>3 regardless of the date, I should say?</p> <p>4 Q. Yes. Yes.</p> <p>5 A. So I testified in the Echeverria</p> <p>6 case. And I testified in the Ingham case. And</p> <p>7 Forrest, I get confused because it was -- I think</p> <p>8 it was originally like a 12 plaintiff case and</p> <p>9 then certain things got pulled out. So I think</p> <p>10 that's it, though.</p> <p>11 Q. Okay. You list here for 2024 a</p> <p>12 deposition you gave in the Archer case in the</p> <p>13 state court of Clayton County, Georgia. When did</p> <p>14 you give that deposition?</p> <p>15 A. Earlier this year, I believe. It</p> <p>16 was -- yeah, earlier this year. I don't recall</p> <p>17 the month.</p> <p>18 Q. Are you -- have you been asked to</p> <p>19 testify at trial?</p> <p>20 A. Yes.</p> <p>21 Q. And when is that trial?</p> <p>22 A. I believe trial starts at the -- in</p> <p>23 August.</p> <p>24 Q. Okay. Are there any other cases</p>
<p style="text-align: right;">Page 43</p> <p>1 listing. In addition to what you've listed</p> <p>2 here -- let me strike that and start again.</p> <p>3 On the current exhibit, would it be</p> <p>4 fair to strike out Forrest and put in Giese,</p> <p>5 et al., underneath that 2021 reference?</p> <p>6 A. Giese, et al., yes.</p> <p>7 But then there was also a case</p> <p>8 of -- I believe her first name was Vicki, I</p> <p>9 think. It was Vicki Forrest, and that was an</p> <p>10 individual plaintiff. And I think --</p> <p>11 Q. Correct.</p> <p>12 A. -- that was also venued in St.</p> <p>13 Louis, if I'm not mistaken.</p> <p>14 Q. You are correct, and that case was</p> <p>15 in, you know, 2019.</p> <p>16 A. Oh, okay. Sorry. Okay.</p> <p>17 Q. And you also -- I was going to ask</p> <p>18 you about that. You also testified in the Brower</p> <p>19 case in 2019, correct, in Atlanta?</p> <p>20 A. Yes.</p> <p>21 Q. And you testified -- I think those</p> <p>22 are the -- let me ask, are there any other talc</p> <p>23 cases in addition to the ones you've listed here</p> <p>24 on Exhibit 6 plus Brower, plus Forrest, that</p>	<p style="text-align: right;">Page 45</p> <p>1 that you've been disclosed as an expert but you</p> <p>2 have not yet provided either deposition testimony</p> <p>3 or trial testimony?</p> <p>4 MS. CURRY: Object to the form.</p> <p>5 Only disclose cases in which</p> <p>6 you've actually been disclosed to the</p> <p>7 other side already as an expert witness.</p> <p>8 MS. O'DELL: And, Dawn, that was</p> <p>9 my question, just to be -- I want to</p> <p>10 make sure my question was clear.</p> <p>11 BY MS. O'DELL:</p> <p>12 Q. I just -- I'm not asking for</p> <p>13 anything other than cases where you've been</p> <p>14 disclosed.</p> <p>15 A. On behalf of Johnson &amp; Johnson?</p> <p>16 Q. Correct.</p> <p>17 A. I've been disclosed in a case, I</p> <p>18 believe the plaintiff's name is Baker.</p> <p>19 Q. And where is that case pending?</p> <p>20 A. In Canada. And Archer we already</p> <p>21 covered, so...</p> <p>22 Q. Thank you, Dr. Saenz. You can put</p> <p>23 that aside.</p> <p>24 All right. Let's turn again to</p>



<p style="text-align: right;">Page 46</p> <p>1 Exhibit 2, your expert report.</p> <p>2 And if you'll forgive me just a</p> <p>3 moment while I shuffle some things around.</p> <p>4 So I'd like for you to turn,</p> <p>5 please, Dr. Saenz, to the portion of your report</p> <p>6 reviewing risk factors, really starting at</p> <p>7 page 5. And I will ask you some questions,</p> <p>8 general questions, and then I'm going to ask you</p> <p>9 some questions also about the Converse case, and</p> <p>10 so they will be hopefully clear but somewhat</p> <p>11 intermingled in order to have some efficiency.</p> <p>12 And specifically, I want to start</p> <p>13 with genetics and your opinions starting on</p> <p>14 page 5 regarding genetics. Is it your view,</p> <p>15 Dr. Saenz, that all ovarian cancer cases are</p> <p>16 caused by genetic mutations?</p> <p>17 MS. CURRY: Object to the form.</p> <p>18 THE WITNESS: Germline or</p> <p>19 somatic?</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. I'll start with germline.</p> <p>22 A. No.</p> <p>23 Q. And so you agree that some ovarian</p> <p>24 cancers are a result of somatic or acquired</p>	<p style="text-align: right;">Page 48</p> <p>1 and those somatic mutations are not in</p> <p>2 every cell in her body. They're just in</p> <p>3 the tumors.</p> <p>4 BY MS. O'DELL:</p> <p>5 Q. Yes, and this is sometimes referred</p> <p>6 to as the -- the two hit or multiple hit process</p> <p>7 that have a germline mutation that's in every</p> <p>8 cell of the patient that have acquired mutations,</p> <p>9 and they result in -- or let me change that since</p> <p>10 that's -- you didn't like that language.</p> <p>11 But it culminates -- that</p> <p>12 accumulation of mutations culminates in ovarian</p> <p>13 cancer. That would be sort of an accurate</p> <p>14 description of what occurs, correct?</p> <p>15 MS. CURRY: Object to the form.</p> <p>16 THE WITNESS: I don't agree with</p> <p>17 that. Knudson's two-hit hypothesis</p> <p>18 really didn't pertain to having a</p> <p>19 germline mutation and then accumulating</p> <p>20 additional somatic mutations. Knudson's</p> <p>21 two-hit hypothesis came out of the fact</p> <p>22 that we have two alleles for every gene</p> <p>23 in our body.</p> <p>24 And so knocking out just one of</p>
<p style="text-align: right;">Page 47</p> <p>1 mutations?</p> <p>2 A. I think that the majority of</p> <p>3 ovarian cancers are -- have somatic or acquired</p> <p>4 mutations. Even cancers that have germline</p> <p>5 mutations with them can have additional acquired</p> <p>6 or somatic mutations.</p> <p>7 Q. In other words, a patient, to use</p> <p>8 language that you have used, a patient could have</p> <p>9 an acquired -- excuse me, a germline mutation,</p> <p>10 like a BRCA mutation, for example, and not</p> <p>11 develop ovarian cancer. True?</p> <p>12 A. True.</p> <p>13 Q. And that individual having a</p> <p>14 germline mutation such as BRCA could have</p> <p>15 acquired mutations, multiple acquired mutations</p> <p>16 over the course of their life that result in</p> <p>17 ovarian cancer. True?</p> <p>18 MS. CURRY: Object to the form.</p> <p>19 THE WITNESS: I -- I don't know</p> <p>20 that it -- "results" is a word that you</p> <p>21 said. I mean, I do know that when we do</p> <p>22 molecular profiling of ovarian cancers</p> <p>23 on patients, it's not uncommon to find</p> <p>24 somatic mutations within those tumors,</p>	<p style="text-align: right;">Page 49</p> <p>1 the alleles with a mutation isn't enough</p> <p>2 for that mutation to effectually allow a</p> <p>3 cancer to develop. Both alleles need to</p> <p>4 either be mutated and defective or</p> <p>5 functionally defective for that allele</p> <p>6 to become nonfunctional. I mean, we</p> <p>7 know that it doesn't take just two</p> <p>8 mutations to develop a cancer, but</p> <p>9 that's where that hypothesis came from.</p> <p>10 BY MS. O'DELL:</p> <p>11 Q. It could take multiple mutations to</p> <p>12 develop a cancer.</p> <p>13 A. For a cancer to develop?</p> <p>14 Q. True?</p> <p>15 A. Yes, I agree with that.</p> <p>16 MS. O'DELL: And I want to mark</p> <p>17 now what I believe is Exhibit 7.</p> <p>18 And if, Paula, you would help me</p> <p>19 make sure I number correctly, that would</p> <p>20 be great. But it's -- it's an ACOG</p> <p>21 document entitled "Hereditary Breast and</p> <p>22 Ovarian Cancer Syndrome."</p> <p>23 (Exhibit No. 7 was marked for</p> <p>24 identification.)</p>

<p style="text-align: right;">Page 50</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. Dr. Saenz, do you have that in</p> <p>3 front of you now?</p> <p>4 A. I do.</p> <p>5 Q. Okay. And we've marked it as</p> <p>6 Exhibit 7. Are you familiar with this document?</p> <p>7 A. I'm sure I've seen it before or a</p> <p>8 version of it, but I haven't reviewed it</p> <p>9 recently.</p> <p>10 Q. Okay. And this is a document</p> <p>11 published by -- jointly by the American College</p> <p>12 of Obstetricians and Gynecologists and the</p> <p>13 Society of Gynecologic Oncology. True?</p> <p>14 A. Yes, that's what it says at the</p> <p>15 top.</p> <p>16 Q. And it is an ACOG Practice</p> <p>17 Bulletin, and it's dated in this copy September</p> <p>18 of 2017. Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. And let me ask you just from your</p> <p>21 perspective, Dr. Saenz, how do you define</p> <p>22 "hereditary breast and ovarian cancer syndrome"?</p> <p>23 A. So hereditary breast and ovarian</p> <p>24 cancer syndrome is a designation of patients</p>	<p style="text-align: right;">Page 52</p> <p>1 suppresser genes that encode proteins that</p> <p>2 function in the DNA repair process. Individuals</p> <p>3 with hereditary breast and ovarian cancer</p> <p>4 syndrome inherit one defective allele in BRCA1 or</p> <p>5 BRCA2 from their father or mother, but they have</p> <p>6 a second functional allele. If the second allele</p> <p>7 becomes nonfunctional as a result of a somatic</p> <p>8 mutation, cancer can develop. This is called the</p> <p>9 two-hit hypothesis."</p> <p>10 Do you agree with those statements,</p> <p>11 Dr. Saenz?</p> <p>12 A. I mean, I think as a summary and</p> <p>13 what they're referring to is what I quoted</p> <p>14 before, which was Knudson's original two-hit</p> <p>15 hypothesis, which dates back to 1971. But what</p> <p>16 we know --</p> <p>17 Q. Right.</p> <p>18 A. -- about cancer biology now is a</p> <p>19 lot more than what Knudson proposed in 1971</p> <p>20 because BRCA1 and 2 weren't even characterized in</p> <p>21 1971.</p> <p>22 Q. But you agree with the concept that</p> <p>23 it takes -- it's a combination often between an</p> <p>24 inherited mutation and a series of acquired</p>
<p style="text-align: right;">Page 51</p> <p>1 being at risk for the development of breast and</p> <p>2 ovarian cancer, which includes fallopian tube,</p> <p>3 primary peritoneal, and often other malignancies</p> <p>4 as well, such as melanoma or pancreatic cancer,</p> <p>5 because they have been identified as carrying a</p> <p>6 certain genetic mutation which predisposes them</p> <p>7 to those malignancies and places them at an</p> <p>8 increased risk of developing those malignancies</p> <p>9 over the course of their lifetime. It's not</p> <p>10 actually just limited to women. Men can also be</p> <p>11 affected by these syndromes.</p> <p>12 Q. But are men affected by hereditary</p> <p>13 breast and ovarian cancer syndrome?</p> <p>14 A. Yes.</p> <p>15 Q. And -- and -- well, I'm curious to</p> <p>16 ask you the question, but I'm not going to do it</p> <p>17 because it's not necessarily pertinent for today,</p> <p>18 so maybe another time.</p> <p>19 Let me direct you to the left-hand</p> <p>20 column on page 1, and under Background, BRCA1</p> <p>21 and 2. Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. And at about the lower half of that</p> <p>24 paragraph, it says: "Both BRCA genes are tumor</p>	<p style="text-align: right;">Page 53</p> <p>1 mutations that lead to the development of ovarian</p> <p>2 cancer?</p> <p>3 MS. CURRY: Object to the form.</p> <p>4 BY MS. O'DELL:</p> <p>5 Q. We agree with that -- I think</p> <p>6 that's what you said before, and I'm just trying</p> <p>7 to repeat it.</p> <p>8 A. I said not in the majority of</p> <p>9 ovarian cancers, because even here they say -- or</p> <p>10 they're saying that 9 to 24 percent of ovarian</p> <p>11 cancers have a germline mutation within them. So</p> <p>12 that would mean that 76 percent of the ovarian</p> <p>13 cancers that develop, there's no identified</p> <p>14 germline mutation.</p> <p>15 Q. And then in those patients that</p> <p>16 don't have an identified germline mutation, then</p> <p>17 there are somatic mutations that accumulate --</p> <p>18 that result in the development of ovarian cancer.</p> <p>19 Would you agree with that?</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 THE WITNESS: I believe that it</p> <p>22 is -- yes, it is an accumulation of</p> <p>23 somatic mutations that we find in</p> <p>24 ovarian cancers.</p>



<p style="text-align: right;">Page 54</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. And if you'll turn to page 2,</p> <p>3 please. And I want to direct you, please, to</p> <p>4 Table 1.</p> <p>5 A. Yes.</p> <p>6 Q. And it has a listing of genetic</p> <p>7 mutations associated with hereditary breast and</p> <p>8 ovarian cancer syndrome. Correct?</p> <p>9 A. Yes.</p> <p>10 Q. And if you'll look, it lists the</p> <p>11 gene on the leftmost column, and then it has a</p> <p>12 column toward the right that describes the</p> <p>13 ovarian cancer risk associated with that gene.</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And in the case of the ATM gene,</p> <p>17 there's no increased risk of ovarian cancer if an</p> <p>18 individual has that inherited mutation, correct?</p> <p>19 MS. CURRY: Object to the form.</p> <p>20 THE WITNESS: That's what this</p> <p>21 table lists, but this table is actually</p> <p>22 out of date.</p> <p>23 BY MS. O'DELL:</p> <p>24 Q. Okay. And what's your basis for</p>	<p style="text-align: right;">Page 56</p> <p>1 reducing surgery is being recommended for. It</p> <p>2 hasn't yet. PALB2 has in the most recent NCCN,</p> <p>3 but ATM is actually being reconsidered for its</p> <p>4 risk.</p> <p>5 Q. So that's preliminary at this</p> <p>6 point, there's been no final determination</p> <p>7 regarding ATM, correct?</p> <p>8 A. There's not --</p> <p>9 MS. CURRY: Object to the form.</p> <p>10 THE WITNESS: Sorry. There's</p> <p>11 not a final national recommendation at</p> <p>12 this juncture, but it is being</p> <p>13 investigated.</p> <p>14 BY MS. O'DELL:</p> <p>15 Q. Okay. Looking at this table,</p> <p>16 putting it in the context of epithelial ovarian</p> <p>17 cancer, are there any other disagreements you</p> <p>18 have with this particular table?</p> <p>19 A. Well, I'm --</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 THE WITNESS: I'm not</p> <p>22 disagreeing, Ms. O'Dell. I'm just</p> <p>23 telling you that this was published in</p> <p>24 2017, and the most recent national</p>
<p style="text-align: right;">Page 55</p> <p>1 saying the table is out of date, Dr. Saenz?</p> <p>2 A. The most current NCCN guidelines</p> <p>3 actually now classify PALB2 as carrying an</p> <p>4 increased ovarian cancer risk. In here it says</p> <p>5 no increased risk.</p> <p>6 And the most recent NCCN guidelines</p> <p>7 also say that women with PALB2 mutations should</p> <p>8 now be offered risk reducing surgery.</p> <p>9 Also, CHEK2 has been associated</p> <p>10 with a risk of developing granulosis cell tumors,</p> <p>11 not epithelial tumors as we have been primarily</p> <p>12 talking about here today. They don't recommend</p> <p>13 prophylactic surgery, but there is an association</p> <p>14 in the literature with granulosis cell tumors.</p> <p>15 Q. But not just -- so the record is</p> <p>16 clear, so I'm tracking what you're saying, not</p> <p>17 epithelial ovarian cancer.</p> <p>18 A. That's correct.</p> <p>19 Q. Okay.</p> <p>20 A. And ATM is actually now being</p> <p>21 looked at critically as potentially increasing</p> <p>22 the risk of epithelial ovarian cancers by 2 to 3</p> <p>23 percent, and is actually being discussed as</p> <p>24 potentially being one of the next genes that risk</p>	<p style="text-align: right;">Page 57</p> <p>1 guidelines that we have from 2024 are</p> <p>2 different than what this table shows.</p> <p>3 That's --</p> <p>4 BY MS. O'DELL:</p> <p>5 Q. Okay. Any others that you want to</p> <p>6 point out that you think the present -- present</p> <p>7 data --</p> <p>8 A. Has been updated?</p> <p>9 Q. Yeah, or different.</p> <p>10 A. No.</p> <p>11 Q. Okay. And if you will turn,</p> <p>12 Dr. Saenz, to page 17, you will see on page 17 a</p> <p>13 box with some information regarding the review of</p> <p>14 literature that was done in the preparation for</p> <p>15 this bulletin.</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. And it describes at the top the</p> <p>19 Medline database, the Cochrane Library, and</p> <p>20 ACOG's own internal resources -- resources and</p> <p>21 documents were used to conduct a literature</p> <p>22 search to locate relevant articles published</p> <p>23 between January 2000 and January -- excuse me,</p> <p>24 May 2017.</p>

<p style="text-align: right;">Page 58</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And it goes on to describe some of</p> <p>4 what was reviewed, and then in the second</p> <p>5 paragraph, it says: "Studies were reviewed and</p> <p>6 evaluated for quality according to the method</p> <p>7 outlined by the U.S. Preventive Services Task</p> <p>8 Force."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And it gives levels of evidence</p> <p>12 there in the -- in this box, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And if you'll look at level Roman</p> <p>15 numeral II-2, it states: "Evidence obtained from</p> <p>16 well-designed cohort or case-control studies,</p> <p>17 preferably from more than one center research</p> <p>18 group."</p> <p>19 Did I read that correctly?</p> <p>20 A. You left out the word "analytic,"</p> <p>21 but otherwise, yes.</p> <p>22 Q. Yes, I'm sorry. I will read it</p> <p>23 again.</p> <p>24 A. No worries.</p>	<p style="text-align: right;">Page 60</p> <p>1 beginning at the top, there's a sentence about</p> <p>2 midway or a third down that starts "To date." Do</p> <p>3 you see that sentence?</p> <p>4 A. Yes.</p> <p>5 Q. "To date, roughly 16 different</p> <p>6 genes have been identified in this cluster, but</p> <p>7 new genes are being identified and added to</p> <p>8 testing panels every year."</p> <p>9 And you go on to say: "In the</p> <p>10 mid-1990s we only tested for two genes, BRCA1 and</p> <p>11 2. By contrast, expanded panel testing currently</p> <p>12 available through many commercial labs examine</p> <p>13 more than 25 genes."</p> <p>14 My question to you is, in your</p> <p>15 opinion, what is the most reliable source in</p> <p>16 listing of genes that you believe to be</p> <p>17 pathogenic to ovarian cancer?</p> <p>18 MS. CURRY: Object to the form.</p> <p>19 THE WITNESS: I would say the</p> <p>20 most reliable and up-to-date source are</p> <p>21 the NCCN guidelines.</p> <p>22 BY MS. O'DELL:</p> <p>23 Q. Are there any others that you</p> <p>24 believe are authoritative and reliable that you</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. I didn't mean to skip a word.</p> <p>2 "Evidence obtained from</p> <p>3 well-designed cohort or case-control analytic</p> <p>4 studies, preferably from more than one center or</p> <p>5 research group."</p> <p>6 Did I get it right that time?</p> <p>7 A. Yes.</p> <p>8 Q. Okay, good.</p> <p>9 And you would agree then in</p> <p>10 relation to talc and ovarian cancer that there</p> <p>11 have been cohort and case-control analytic</p> <p>12 studies from more than one center or research</p> <p>13 group published over the last 40 years. True?</p> <p>14 A. Yes.</p> <p>15 Q. And in this chart from ACOG, the</p> <p>16 well- designed cohort and case-control analytic</p> <p>17 studies are placed on the same level of evidence,</p> <p>18 correct?</p> <p>19 A. They're both classified as evidence</p> <p>20 II-2, yes.</p> <p>21 Q. I want to put that aside,</p> <p>22 Dr. Saenz.</p> <p>23 Let me ask you to turn back to your</p> <p>24 report on page 6. You state in the paragraph</p>	<p style="text-align: right;">Page 61</p> <p>1 rely on in reaching your opinions about the genes</p> <p>2 that are pathetic for ovarian cancer?</p> <p>3 MS. CURRY: Object to the form.</p> <p>4 THE WITNESS: I mean, there are</p> <p>5 other organizations such as</p> <p>6 organizations for genetic research and</p> <p>7 genetic counselors, but I don't utilize</p> <p>8 those the way that I utilize the NCCN</p> <p>9 guidelines.</p> <p>10 MS. CURRY: I just want to note</p> <p>11 for the record that, Leigh, I'm giving a</p> <p>12 little bit of leeway here, but -- no pun</p> <p>13 intended, but the sections that you're</p> <p>14 reading from on the report were actually</p> <p>15 already in the 2019 general causation</p> <p>16 report.</p> <p>17 And so it was my understanding</p> <p>18 that we're here to talk about anything</p> <p>19 new, just going forward, and obviously</p> <p>20 any of the case-specific information.</p> <p>21 MS. O'DELL: That's fair enough.</p> <p>22 She -- Dr. Saenz changed some of the</p> <p>23 material above that, and -- but I'm</p> <p>24 happy to couch my questions in terms of</p>

<p style="text-align: right;">Page 62</p> <p>1 2019.</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. Since 2019 and today, Dr. Saenz, is</p> <p>4 it your testimony that what you refer to as the</p> <p>5 authoritative sort of source for pathogenic genes</p> <p>6 is the NCCN guidelines? Is that an accurate</p> <p>7 restatement of your testimony?</p> <p>8 MS. CURRY: Object to the form.</p> <p>9 THE WITNESS: The NCCN</p> <p>10 guidelines are what I use as my resource</p> <p>11 for the identification of genes that are</p> <p>12 placing women at an increased risk of</p> <p>13 developing ovarian cancer.</p> <p>14 I mean, it's not the only thing</p> <p>15 I've ever looked at, Leigh. I don't</p> <p>16 want to say that's the only reference</p> <p>17 that I use, right. I read other papers</p> <p>18 and things. That's how I know that ATM</p> <p>19 is being investigated because that</p> <p>20 hasn't changed in NCCN yet. But I at,</p> <p>21 for example, this juncture of my career</p> <p>22 would not prophylactically take the</p> <p>23 ovaries out of a woman with an ATM</p> <p>24 mutation because I don't believe I have</p>	<p style="text-align: right;">Page 64</p> <p>1 to have more lifetime ovulatory cycles than women</p> <p>2 that have fewer, but that the risk reduction from</p> <p>3 either birth control pills or breastfeeding or</p> <p>4 pregnancy is magnitudes greater than would simply</p> <p>5 be accounted for by the number of suppressed</p> <p>6 ovulatory cycles.</p> <p>7 So it doesn't make sense</p> <p>8 biologically that it's simply a matter of</p> <p>9 ovulating. There has to be -- there's another</p> <p>10 biologic mechanism that we just haven't</p> <p>11 elucidated yet that is related to an increased</p> <p>12 number of ovulatory cycles leading to an</p> <p>13 increased risk of ovarian cancer.</p> <p>14 And so I came across the Huang</p> <p>15 paper because I was looking up how lifetime</p> <p>16 ovulatory cycles related to ovarian cancer risk</p> <p>17 development, and what Huang did was also measure</p> <p>18 women's CRP levels, which CRP being C-reactive</p> <p>19 protein is a marker of chronic systemic</p> <p>20 inflammation. And paradoxically, what Huang</p> <p>21 found was the more lifetime ovulatory cycles a</p> <p>22 woman had, and they measured them in five-year</p> <p>23 increments, the lower their level of C-reactive</p> <p>24 protein. And so they did not correlate.</p>
<p style="text-align: right;">Page 63</p> <p>1 support from a national agency to</p> <p>2 endorse that yet. But in the course of</p> <p>3 the last year or two, I've probably</p> <p>4 operated on five women with PALB2</p> <p>5 mutations because the guidelines have</p> <p>6 changed.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. All right. I'm going to ask you to</p> <p>9 turn, Dr. Saenz, to your -- to page 8 of your</p> <p>10 report.</p> <p>11 And you added here in your report a</p> <p>12 reference 25 to the Huang and colleagues study</p> <p>13 that was published in 2020.</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And for what purpose did you add</p> <p>17 that -- that study to your discussion of early</p> <p>18 menarche, late menopause risk factor description?</p> <p>19 A. I think there are a couple of</p> <p>20 reasons. One is the fact that the incessant</p> <p>21 ovulation hypothesis, which, you know, has been</p> <p>22 discussed numerous times before, but it goes back</p> <p>23 to demonstrating that there is an increased risk</p> <p>24 of developing ovarian cancer in women that seem</p>	<p style="text-align: right;">Page 65</p> <p>1 If ovulatory cycles number were</p> <p>2 increasing systemic inflammation risk, then the</p> <p>3 authors hypothesized that the C-reactive protein</p> <p>4 levels should have been higher and correlating</p> <p>5 directly with the number of ovulatory cycles.</p> <p>6 But what they found actually was the more</p> <p>7 ovulatory cycles, the lower levels of C-reactive</p> <p>8 protein. And so the authors concluded that</p> <p>9 lifetime ovulatory cycles are not contributing to</p> <p>10 the risk of ovarian cancer through the</p> <p>11 development of chronic systemic inflammation</p> <p>12 because they found lower C-reactive protein</p> <p>13 levels in those women.</p> <p>14 Q. In the Huang paper, the premise of</p> <p>15 the paper was that inflammation as a result of</p> <p>16 lifetime ovulatory cycles increases inflammation,</p> <p>17 and inflammation is associated with ovarian</p> <p>18 cancer. That was the premise of the study.</p> <p>19 Fair?</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 THE WITNESS: That was their</p> <p>22 hypothesis, that the ovulatory events</p> <p>23 were increasing systemic inflammation,</p> <p>24 and so as a marker of that, they</p>

<p style="text-align: right;">Page 66</p> <p>1 investigated CRP levels, and they found</p> <p>2 the exact opposite of what the</p> <p>3 hypothesis was.</p> <p>4 BY MS. O'DELL:</p> <p>5 Q. You would agree, Dr. Saenz, that</p> <p>6 reproductive events such as ovulation and</p> <p>7 menstruation trigger an acute inflammatory</p> <p>8 cascade because of the repeated damage and repair</p> <p>9 to the ovarian surface.</p> <p>10 MS. CURRY: Object to the form.</p> <p>11 THE WITNESS: I -- I don't -- if</p> <p>12 you're talking about one event in</p> <p>13 isolation, then it's an acute event, but</p> <p>14 the chronicity is because these events</p> <p>15 are happening monthly over many, many</p> <p>16 years.</p> <p>17 BY MS. O'DELL:</p> <p>18 Q. Yes. So it's an acute event</p> <p>19 happening on a monthly basis that results in a</p> <p>20 chronic inflammatory process. Fair?</p> <p>21 MS. CURRY: Object to the form.</p> <p>22 THE WITNESS: That's what the</p> <p>23 authors hypothesized, but they didn't</p> <p>24 find evidence of that.</p>	<p style="text-align: right;">Page 68</p> <p>1 MS. CURRY: Object to the form.</p> <p>2 THE WITNESS: I think most</p> <p>3 likely, but I've not actually looked for</p> <p>4 that.</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. That's been reported in literature,</p> <p>7 right?</p> <p>8 A. Yes, that's true.</p> <p>9 Q. And that would be a generally</p> <p>10 accepted understanding of what happens at the</p> <p>11 time of ovulation, that there is damage to the</p> <p>12 surface of the ovary, and resulting repair that</p> <p>13 is -- involves an inflammatory process. True,</p> <p>14 that's generally accepted?</p> <p>15 MS. CURRY: Object to the form.</p> <p>16 THE WITNESS: I agree that</p> <p>17 there's damage to the ovary and then</p> <p>18 there is a repair process. There is a</p> <p>19 cascade there, yes.</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. An inflammatory cascade, right?</p> <p>22 MS. CURRY: Object to the form.</p> <p>23 THE WITNESS: An acute</p> <p>24 inflammatory cascade?</p>
<p style="text-align: right;">Page 67</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. And would you agree -- I mean, you</p> <p>3 say that was their hypothesis. Would you agree</p> <p>4 that ovulation and menstruation trigger an</p> <p>5 inflammatory process due to the damage and repair</p> <p>6 to the ovarian surface epithelium?</p> <p>7 MS. CURRY: Object to the form.</p> <p>8 THE WITNESS: I don't</p> <p>9 necessarily know that. I don't think</p> <p>10 menstruation means the sloughing of the</p> <p>11 endometrium has nothing to do with</p> <p>12 what's going on with the ovulatory</p> <p>13 events which occur during a different</p> <p>14 phase of the cycle. I do think that</p> <p>15 ovulation causes damage to the surface</p> <p>16 of the ovary and that gets repaired.</p> <p>17 But we in looking at the ovaries of</p> <p>18 women and sites of ovulation, we don't</p> <p>19 see evidence of chronic damage or even</p> <p>20 acute -- not acute, but chronic damage.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. But there would be evidence of</p> <p>23 acute damage to the -- an acute inflammation at</p> <p>24 the time of ovulation. True?</p>	<p style="text-align: right;">Page 69</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. Yes.</p> <p>3 A. Okay. Yes.</p> <p>4 Q. Let me ask you to take a look at</p> <p>5 the Huang paper, Dr. Saenz.</p> <p>6 MS. O'DELL: And I will mark</p> <p>7 that as Exhibit 8.</p> <p>8 (Exhibit No. 8 was marked for</p> <p>9 identification.)</p> <p>10 BY MS. O'DELL:</p> <p>11 Q. Do you have that in front of you,</p> <p>12 Dr. Saenz?</p> <p>13 A. Yes, ma'am.</p> <p>14 Q. And this is the study that we've</p> <p>15 been talking about and that you referred to</p> <p>16 your -- you refer to your report on page -- page</p> <p>17 8 and -- excuse me, on page 8 of your report.</p> <p>18 And then I'd like for you to turn, please, to</p> <p>19 what's identified as page 667 in the upper right</p> <p>20 corner.</p> <p>21 And if you'll look on the left-hand</p> <p>22 side, Dr. Saenz, in the Discussion section. Do</p> <p>23 you see where I'm looking?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 70</p> <p>1 Q. And I think it's three sentences  2 down, it says: "The strength of the association  3 between LOY and CRP," meaning lifetime ovulations  4 and C-reactive protein, "was comparable to that  5 for other well-established inflammatory  6 exposures, including physical activity and an  7 inflammatory diet, the weaker than the  8 association for BMI, suggesting that LOY may be a  9 potential marker for systemic inflammation in  10 women."  11 Did I read that correctly?  12 A. Yes.  13 Q. And it goes on to say on the next  14 page, page 668, that -- in the Summary paragraph  15 at the end, second sentence: "Our results  16 suggest that reproductive history may be an  17 important source of inflammation in women that is  18 comparable to diet and physical activity."  19 Did I read that correctly?  20 A. Yes.  21 Q. And throughout this study,  22 Dr. Saenz, the researchers were focused on  23 inflammation as a contributor to ovarian cancer,  24 correct?</p>	<p style="text-align: right;">Page 72</p> <p>1 that part of the reason they studied lifetime  2 ovulations is because of the understanding that  3 inflammation is associated with an increased risk  4 of ovarian cancer. True?  5 MS. CURRY: Object to the form.  6 THE WITNESS: No, I -- I don't  7 actually agree with that. The --  8 BY MS. O'DELL:  9 Q. Now, please, if I could just --  10 forgive me, I'll try not to do that. But let me  11 just ask to make sure my question was clear.  12 I'm not asking -- I know you may  13 have a different opinion, but I'm asking about  14 what the authors in the premise of the paper as  15 they describe it, one of the premises -- one of  16 the main premises of the paper is that lifetime  17 ovulatory years and an increase in inflammation  18 results in a higher risk of ovarian cancer.  19 True?  20 MS. CURRY: Object to the form.  21 THE WITNESS: No, that's not  22 their hypothesis. The hypothesis has to  23 do with trying to link why an increased  24 number of ovulatory years and the acute</p>
<p style="text-align: right;">Page 71</p> <p>1 MS. CURRY: Object to the form.  2 THE WITNESS: No, that was their  3 hypothesis. Throughout this study they  4 were focused on the number of ovulatory  5 years and how that -- those acute events  6 could have led to the development of  7 systemic chronic inflammation, and  8 looking at the markers for that, and  9 whether or not they were there. They  10 were not actually looking at ovarian  11 cancer. They were essentially trying to  12 identify a mechanism by which Fathalla's  13 original hypothesis would be related.  14 Q. And at any -- and they say in this  15 paper that lifetime ovulatory years has been  16 consistently associated with a higher risk of  17 ovarian cancer. That's one of the underlying  18 premises of the study. True?  19 MS. CURRY: Where are you  20 reading from? Sorry, Leigh.  21 MS. O'DELL: I'm reading from  22 page 660.  23 BY MS. O'DELL:  24 Q. But what I'm asking, Dr. Saenz, is</p>	<p style="text-align: right;">Page 73</p> <p>1 inflammation that occurs as a result of  2 those individual ovulatory events, does  3 that result in systemic inflammation,  4 chronic, and trying to identify markers  5 that would show that there is some link  6 between the acute inflammatory events  7 with each ovulatory event and the  8 development of chronic systemic  9 ovulation that may be related to ovarian  10 cancer risk.  11 But it's not -- they weren't  12 investigating the inflammation, per se.  13 They were investigating whether or not  14 there's evidence that ovulation and the  15 number of ovulatory events leads to the  16 development of systemic chronic  17 inflammation, and they found the  18 opposite.  19 BY MS. O'DELL:  20 Q. And as noted by the authors,  21 inflammation has a role in the development of  22 ovarian cancer. True?  23 MS. CURRY: Object to the form.  24 THE WITNESS: Where are you</p>



<p style="text-align: right;">Page 74</p> <p>1 reading from?</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. I'm asking just -- that's my own</p> <p>4 question.</p> <p>5 A. No, that's not their hypothesis.</p> <p>6 Q. You don't believe that they</p> <p>7 believed -- these authors, these researchers on</p> <p>8 Exhibit 8, are you saying that they as a part of</p> <p>9 their research did not consider inflammation as a</p> <p>10 mediator of ovarian cancer?</p> <p>11 MS. CURRY: Object to the form,</p> <p>12 calls for speculation.</p> <p>13 THE WITNESS: The hypothesis of</p> <p>14 these authors was that the development</p> <p>15 of acute inflammation that occurs with</p> <p>16 each ovulatory event could potentially</p> <p>17 result in evidence of chronic systemic</p> <p>18 inflammation, and they were trying to</p> <p>19 see if they could identify that and</p> <p>20 thereby link it to the increased risk of</p> <p>21 ovarian cancer that we see in women with</p> <p>22 more ovulatory events, and what they</p> <p>23 found with their data was actually the</p> <p>24 opposite.</p>	<p style="text-align: right;">Page 76</p> <p>1 study who weren't ovulating either. This was a</p> <p>2 systemic assay. It wasn't a localized assay at</p> <p>3 the level of the ovary.</p> <p>4 Q. Did you consider the commentary by</p> <p>5 Dr. Joellen Schildkraut about the Huang paper?</p> <p>6 A. I don't believe I've seen that.</p> <p>7 Q. Have you seen other studies</p> <p>8 regarding -- have you seen and considered other</p> <p>9 studies regarding lifetime ovulations that</p> <p>10 conclude exactly the opposite of what Huang and</p> <p>11 her colleagues concluded?</p> <p>12 MS. CURRY: Object to the form.</p> <p>13 THE WITNESS: I think you would</p> <p>14 have to refer me to a specific study,</p> <p>15 because I don't -- I don't recall off</p> <p>16 the top of my head any specific study in</p> <p>17 that level of detail.</p> <p>18 BY MS. O'DELL:</p> <p>19 Q. Dr. Saenz, I want to turn your</p> <p>20 attention back to Exhibit 3, the comparison.</p> <p>21 A. Are we done with this study, ma'am?</p> <p>22 May I set it aside?</p> <p>23 Q. You can, yeah. Thank you.</p> <p>24 So I want to turn back -- I skipped</p>
<p style="text-align: right;">Page 75</p> <p>1 So they ended up not being able</p> <p>2 to identify that the individual acute</p> <p>3 inflammatory events associated with each</p> <p>4 individual ovulatory event leads to</p> <p>5 evidence of increased systemic</p> <p>6 inflammation.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. Okay. Would you agree with me,</p> <p>9 Dr. Saenz, that C-reactive protein is a</p> <p>10 nonspecific systemic marker of chronic</p> <p>11 inflammation?</p> <p>12 A. Yes.</p> <p>13 Q. And that it is not a measure of the</p> <p>14 localized inflammation that may occur during</p> <p>15 ovulation at the site of the ovary?</p> <p>16 A. I don't know that because I don't</p> <p>17 know that anybody has assayed CRP levels at the</p> <p>18 time of ovulation. So I don't know that.</p> <p>19 Q. Certainly -- but the authors for</p> <p>20 the Huang study were not assaying inflammation --</p> <p>21 localized inflammation at the site of the ovary,</p> <p>22 correct?</p> <p>23 A. That's absolutely correct, because</p> <p>24 they also included postmenopausal women in their</p>	<p style="text-align: right;">Page 77</p> <p>1 something in my notes and I don't want to forget</p> <p>2 it, so I just want to go back to it before we get</p> <p>3 too far away.</p> <p>4 Under your Genetics section, which</p> <p>5 is page 5 in your May 2024 report, and in the</p> <p>6 comparison which we marked as Exhibit 3, turn to</p> <p>7 page 6, and you'll see in Exhibit 3 the</p> <p>8 comparison, Dr. Saenz, under Genetics.</p> <p>9 Are you there with me?</p> <p>10 A. Yes.</p> <p>11 Q. You struck a sentence that says:</p> <p>12 "Approximately 10 percent of women diagnosed with</p> <p>13 ovarian cancer are found to have inherited such a</p> <p>14 deleterious mutation, but when that analysis is</p> <p>15 restricted to women whose ovarian cancer is of</p> <p>16 serous histology, the rate increases to</p> <p>17 approximately 30 percent."</p> <p>18 Why did you strike that?</p> <p>19 A. I thought it was confusing.</p> <p>20 Because there was a point in time when we were</p> <p>21 only sending women with serous histologies for</p> <p>22 germline testing and not all women with</p> <p>23 epithelial ovarian cancers, because the yield of</p> <p>24 finding a germline mutation in a woman with</p>

<p style="text-align: right;">Page 78</p> <p>1 ovarian cancer is higher if you restrict the</p> <p>2 screening to serous histologies. But the current</p> <p>3 NCCN guidelines are actually that all women with</p> <p>4 epithelial ovarian cancer should be screened, and</p> <p>5 so it didn't -- it seemed to me to be a sentence</p> <p>6 that was not needed.</p> <p>7 Q. And no longer in keeping with</p> <p>8 current practice. Fair?</p> <p>9 MS. CURRY: Object to the form.</p> <p>10 THE WITNESS: Correct, not</p> <p>11 consistent with current guidelines.</p> <p>12 It doesn't mean it's not</p> <p>13 factual. It's factual, but not</p> <p>14 consistent with current guidelines.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. What's your -- if it's still</p> <p>17 factual, what's your basis for that opinion? I</p> <p>18 don't see a citation there.</p> <p>19 A. I don't recall what it was, but</p> <p>20 there were papers that looked at screening women</p> <p>21 with high grade serous histologies as opposed to</p> <p>22 all histologies and what percentage of patients</p> <p>23 would have mutations, and the high grade serous</p> <p>24 histologies have a higher rate of having an HRD</p>	<p style="text-align: right;">Page 80</p> <p>1 mark that as, I believe, Exhibit 9.</p> <p>2 And Paula should have that.</p> <p>3 Thank you.</p> <p>4 (Exhibit No. 9 was marked for</p> <p>5 identification.)</p> <p>6 BY MS. O'DELL:</p> <p>7 Q. Just let me know when you are</p> <p>8 ready.</p> <p>9 A. Oh, I'm sorry. Sorry. I'm ready.</p> <p>10 Q. Okay. Dr. Saenz, what was your</p> <p>11 methodology in reaching your case-specific</p> <p>12 opinions for Ms. Converse?</p> <p>13 A. For Ms. Converse, I read through</p> <p>14 all of the medical records that I was provided.</p> <p>15 I reviewed the reports of Dr. Clarke-Pearson,</p> <p>16 Dr. Godleski. I reviewed a plaintiff's expert</p> <p>17 report of, I believe, Dr. Felix. And I might be</p> <p>18 confusing Newsome. I'm sorry.</p> <p>19 MS. CURRY: You said plaintiff</p> <p>20 expert report.</p> <p>21 THE WITNESS: Oh, sorry.</p> <p>22 Defense expert pathologist Dr. Felix.</p> <p>23 I read all the depositions that</p> <p>24 I was provided in this case, and as more</p>
<p style="text-align: right;">Page 79</p> <p>1 germline mutation.</p> <p>2 Q. And you believe that to be 30</p> <p>3 percent?</p> <p>4 A. Yes.</p> <p>5 MS. CURRY: Leigh, I don't know</p> <p>6 if now is a good time, but we've been</p> <p>7 going for over an hour and a half, for a</p> <p>8 very brief break, if that's okay.</p> <p>9 MS. O'DELL: That will be fine.</p> <p>10 Any time, Dr. Saenz, you or</p> <p>11 others need a break, just let me know.</p> <p>12 THE WITNESS: Thank you so much.</p> <p>13 MS. O'DELL: And I'm happy to</p> <p>14 take a break. Thank you.</p> <p>15 What do you say, five minutes?</p> <p>16 MS. CURRY: Five minutes is</p> <p>17 plenty. That's fine.</p> <p>18 (Recess.)</p> <p>19 MS. O'DELL: Let's go back on</p> <p>20 the record.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. Dr. Saenz, I want to ask you to</p> <p>23 turn to the Converse case-specific report.</p> <p>24 MS. O'DELL: And we're going to</p>	<p style="text-align: right;">Page 81</p> <p>1 medical records came in, I kept looking</p> <p>2 at all of those.</p> <p>3 BY MS. O'DELL:</p> <p>4 Q. Okay. And you did not consider the</p> <p>5 expert report of plaintiff's expert John Levy,</p> <p>6 correct?</p> <p>7 A. I did not.</p> <p>8 Q. And you did not consider the expert</p> <p>9 report of -- exposure report of Dr. Bill Longo or</p> <p>10 William Longo for Ms. Converse, correct?</p> <p>11 A. I did not.</p> <p>12 Q. And looking at this case-specific</p> <p>13 expert report for Ms. Converse, based on your</p> <p>14 review of her medical records and other</p> <p>15 information that you mentioned, you did an</p> <p>16 evaluation of the risk factors that she had for</p> <p>17 ovarian cancer, correct?</p> <p>18 A. That's correct.</p> <p>19 Q. You ruled in certain risk factors</p> <p>20 for ovarian cancer you felt that she had, and</p> <p>21 then you ruled out certain risk factors you felt</p> <p>22 that there was no evidence for. True?</p> <p>23 MS. CURRY: Object to the form.</p> <p>24 THE WITNESS: Well, I</p>



<p style="text-align: right;">Page 82</p> <p>1 identified, based on her plaintiff</p> <p>2 profile forms, deposition testimony, her</p> <p>3 treaters, and medical records, certain</p> <p>4 risk factors that are well established</p> <p>5 for ovarian cancer that she seemed to</p> <p>6 have.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. And based on your review of</p> <p>9 Ms. Converse's medical history and other</p> <p>10 information, you concluded that her age, her</p> <p>11 Ashkenazi Jewish heritage, her family history of</p> <p>12 breast cancer and her use of hormone replacement</p> <p>13 therapy were risk factors that she had for</p> <p>14 ovarian cancer, correct?</p> <p>15 MS. CURRY: Object to the form.</p> <p>16 THE WITNESS: As well as the</p> <p>17 endometriosis that was found within her</p> <p>18 surgical specimens, as well as the</p> <p>19 suggestion of a family history, and in</p> <p>20 particular, the family history of her</p> <p>21 mother having at a young age breast</p> <p>22 cancer. That was also another risk</p> <p>23 factor that she had, yes.</p> <p>24 BY MS. O'DELL:</p>	<p style="text-align: right;">Page 84</p> <p>1 opinion or not your opinion?</p> <p>2 A. My opinion is that --</p> <p>3 MS. CURRY: Object to the form.</p> <p>4 THE WITNESS: My opinion is that</p> <p>5 they all increased her risk of</p> <p>6 developing ovarian cancer. I don't have</p> <p>7 any opinion that they worked together,</p> <p>8 but I do believe that they all increased</p> <p>9 her risk of developing ovarian cancer.</p> <p>10 BY MS. O'DELL:</p> <p>11 Q. Ovarian cancer, though, is a</p> <p>12 multifactorial disease, correct?</p> <p>13 A. It can be.</p> <p>14 Q. And it's described in the</p> <p>15 literature many times as a multifactorial</p> <p>16 disease. Fair?</p> <p>17 A. I think that's in the literature.</p> <p>18 Yes, I think that's fair.</p> <p>19 Q. But you've testified in the past,</p> <p>20 and to some degree I think over the last few</p> <p>21 minutes, that you don't know what causes ovarian</p> <p>22 cancer in a particular woman. Correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And in fact, you testified in the</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. And those risk factors, from your</p> <p>2 point of view, contributed to her developing</p> <p>3 ovarian cancer. True?</p> <p>4 MS. CURRY: Object to the form.</p> <p>5 THE WITNESS: So I am not</p> <p>6 assigning causation to any of those risk</p> <p>7 factors in her development of ovarian</p> <p>8 cancer. I am simply saying that she had</p> <p>9 various risk factors that certainly</p> <p>10 increased her risk of developing ovarian</p> <p>11 cancer.</p> <p>12 BY MS. O'DELL:</p> <p>13 Q. And for those particular factors or</p> <p>14 risk factors, would you say they contributed to</p> <p>15 her development of ovarian cancer?</p> <p>16 A. I think they contributed to her</p> <p>17 being at risk for the development of ovarian</p> <p>18 cancer. I cannot point to any one of those</p> <p>19 single risk factors and saying, Aha, there, it's</p> <p>20 that one.</p> <p>21 Q. And I'm definitely not asking you</p> <p>22 that, but would you agree with me that they all</p> <p>23 can work together and contribute to the</p> <p>24 development of her ovarian cancer? Is that your</p>	<p style="text-align: right;">Page 85</p> <p>1 past that you have no idea what causes ovarian</p> <p>2 cancer. True?</p> <p>3 MS. CURRY: Object to the form.</p> <p>4 THE WITNESS: In any one</p> <p>5 particular woman, I have no idea what</p> <p>6 causes ovarian cancer.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. And is it your opinion that there's</p> <p>9 no credible scientific data to support the</p> <p>10 conclusion that talc contributed to</p> <p>11 Ms. Converse's development of ovarian cancer?</p> <p>12 A. Yes, that is my opinion.</p> <p>13 Q. And if -- is there any circumstance</p> <p>14 under which you could conclude that the genital</p> <p>15 application of talc contributes to cause ovarian</p> <p>16 cancer?</p> <p>17 MS. CURRY: Object to the form.</p> <p>18 THE WITNESS: Based on the</p> <p>19 current state of the science, no.</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. If that's the case, Dr. Saenz, that</p> <p>22 based on the science as you evaluate it, that</p> <p>23 talc could never be a contributing cause of a</p> <p>24 woman's ovarian cancer, why did you review all</p>

<p style="text-align: right;">Page 86</p> <p>1 the medical records? Why was it necessary to</p> <p>2 your opinion if your opinion is you already have</p> <p>3 reached the conclusion that talc cannot</p> <p>4 contribute to the development of ovarian cancer?</p> <p>5 A. I was asked to review her medical</p> <p>6 records, her medical history, and her care, and I</p> <p>7 thought it was important for me to identify</p> <p>8 whether or not there were risk factors that she</p> <p>9 had that increased her risk of developing ovarian</p> <p>10 cancer.</p> <p>11 Q. And you listed age as a</p> <p>12 well-established factor for increasing her risk</p> <p>13 of ovarian cancer. True?</p> <p>14 A. Yes.</p> <p>15 Q. And you also listed Ashkenazi</p> <p>16 Jewish heritage, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Endometriosis, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And the use of hormone replacement</p> <p>21 therapy as a well-established risk factor for</p> <p>22 developing ovarian cancer.</p> <p>23 A. Yes.</p> <p>24 Q. True?</p>	<p style="text-align: right;">Page 88</p> <p>1 began to use Johnson's baby powder in 1962 at the</p> <p>2 age of 14, and then continued thereafter to</p> <p>3 approximately 2017.</p> <p>4 Do you recall that?</p> <p>5 A. I'm looking for that, ma'am. I'm</p> <p>6 sorry.</p> <p>7 Do I have that in my report? I</p> <p>8 don't recall that specific testimony, but again,</p> <p>9 I don't have a reason to doubt you.</p> <p>10 Q. And if -- you know, I'm -- I know</p> <p>11 you reviewed her deposition and other materials</p> <p>12 related to Ms. Converse. I'll represent to you</p> <p>13 that's correct.</p> <p>14 A. Okay.</p> <p>15 Q. And would you agree that she used</p> <p>16 Johnson's baby powder in her 20s and 30s?</p> <p>17 A. Yes.</p> <p>18 Q. And we're going to talk about that</p> <p>19 just a little bit later, but that's a time period</p> <p>20 that Dr. O'Brien and her colleagues in her 2024</p> <p>21 study found to be of particular concern for the</p> <p>22 development of ovarian cancer. True?</p> <p>23 MS. CURRY: Object to the form.</p> <p>24 THE WITNESS: That's what they</p>
<p style="text-align: right;">Page 87</p> <p>1 A. Yes.</p> <p>2 Q. Okay.</p> <p>3 A. As well as her family history with</p> <p>4 her mother in particular with breast cancer at a</p> <p>5 young age, and the fact that she had genetic</p> <p>6 testing, and even though the genetic testing</p> <p>7 showed variants of uncertain significance, those</p> <p>8 same two mutations were also found in her mother,</p> <p>9 who had had breast cancer.</p> <p>10 Q. And is it your understanding that</p> <p>11 Ms. Converse used Johnson's baby powder daily,</p> <p>12 and sometimes more often than daily, during her</p> <p>13 menstrual cycle for over 50 years?</p> <p>14 A. I -- I don't recall her specifying</p> <p>15 it during her menstrual cycle, but if that's -- I</p> <p>16 will take you at face value for saying that, if</p> <p>17 that's what her testimony was.</p> <p>18 Q. You would agree with -- you would</p> <p>19 agree with me she used Johnson's baby powder</p> <p>20 daily or near daily for over 50 years, correct?</p> <p>21 A. I don't have that in front of me,</p> <p>22 but I will agree that if that's what she</p> <p>23 reported, then that is what she used.</p> <p>24 Q. And Ms. Converse testified that she</p>	<p style="text-align: right;">Page 89</p> <p>1 reported.</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. And for Ms. Converse, taking my</p> <p>4 representation that it's 55 years, that's what</p> <p>5 the math is from 1962 to 2017, on a daily basis</p> <p>6 if -- 365 days a year, that would be over 20,000</p> <p>7 applications of Johnson's baby powder. True?</p> <p>8 A. I will trust you on your math.</p> <p>9 Q. Okay. I used a calculator. I</p> <p>10 don't trust myself, but I trust a calculator.</p> <p>11 And that would be, based on your</p> <p>12 review of the epidemiological literature, over</p> <p>13 20,000 applications would really be at the</p> <p>14 highest level of exposures for what's been seen</p> <p>15 in the epidemiologic studies. True?</p> <p>16 MS. CURRY: Object to the form.</p> <p>17 THE WITNESS: Well, it's -- I</p> <p>18 think most of the studies have looked at</p> <p>19 20 years or more of application. They</p> <p>20 haven't, you know, quantified the number</p> <p>21 of years more than that. So, yes, that</p> <p>22 would be at the upper limits of when</p> <p>23 they're saying more than 20 years of</p> <p>24 applications.</p>

<p style="text-align: right;">Page 90</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. Yeah, one of the highest usage</p> <p>3 categories. I mean, you can recall, for example,</p> <p>4 in, I believe it was, the Penninkilampi study,</p> <p>5 you will remember they talked about greater than</p> <p>6 3600 applications.</p> <p>7 A. Correct.</p> <p>8 Q. And I believe it was Dr. Cramer's</p> <p>9 study in 2016, colleagues talked about greater</p> <p>10 than 7500 applications for lifetime applications.</p> <p>11 Do you recall that?</p> <p>12 A. Yes.</p> <p>13 Q. And so this would be --</p> <p>14 Ms. Converse's usage at 20,000 times over her</p> <p>15 lifetime would be really at the upper end of</p> <p>16 exposures for what's been seen in the</p> <p>17 epidemiologic studies. True?</p> <p>18 MS. CURRY: Object to the form,</p> <p>19 asked and answered.</p> <p>20 THE WITNESS: Correct.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. And that amount of usage or that</p> <p>23 level of usage was not something that you found</p> <p>24 relevant in your conclusion that talc does not</p>	<p style="text-align: right;">Page 92</p> <p>1 important to your analysis for your causation</p> <p>2 opinion, correct?</p> <p>3 MS. CURRY: Object to the form.</p> <p>4 THE WITNESS: It's not that it</p> <p>5 wasn't important. I mean, I</p> <p>6 documented it --</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. Relevant --</p> <p>9 A. Relevant.</p> <p>10 Q. -- or important.</p> <p>11 A. Well --</p> <p>12 Q. Please --</p> <p>13 A. -- it's not both.</p> <p>14 MS. CURRY: Same objection.</p> <p>15 THE WITNESS: It was not</p> <p>16 relevant to my opinion that talc did not</p> <p>17 contribute to her developing ovarian</p> <p>18 cancer.</p> <p>19 BY MS. O'DELL:</p> <p>20 Q. When you were going through</p> <p>21 Ms. Converse's medical history and her records,</p> <p>22 did you rule out other risk factors that you felt</p> <p>23 were not pertinent to her case -- excuse me --</p> <p>24 were not pertinent to her case? In other words,</p>
<p style="text-align: right;">Page 91</p> <p>1 increase her risk of ovarian cancer. True?</p> <p>2 A. It's not that it's not relevant.</p> <p>3 It's that even that number of applications is not</p> <p>4 supported by the literature as increasing her</p> <p>5 risk of developing ovarian cancer.</p> <p>6 Q. And because from your perspective</p> <p>7 the epidemiologic literature doesn't support an</p> <p>8 association; therefore, her amount of usage was</p> <p>9 not important to your causation conclusion,</p> <p>10 correct?</p> <p>11 MS. CURRY: Object to the form.</p> <p>12 THE WITNESS: So the amount of</p> <p>13 usage that she had is not supported by</p> <p>14 the literature as contributing to her</p> <p>15 developing ovarian cancer.</p> <p>16 BY MS. O'DELL:</p> <p>17 Q. And therefore, not relevant to your</p> <p>18 causation opinion. True?</p> <p>19 A. And therefore, I do not believe</p> <p>20 that talc contributed to her developing ovarian</p> <p>21 cancer.</p> <p>22 Q. And therefore, because you don't</p> <p>23 believe that talc contributed to her development</p> <p>24 of ovarian cancer, the level of usage was not</p>	<p style="text-align: right;">Page 93</p> <p>1 did you rule out early menarche and late</p> <p>2 menopause as relevant to her case?</p> <p>3 MS. CURRY: Object to the form.</p> <p>4 THE WITNESS: So she had</p> <p>5 menarche at age 14, so that wouldn't</p> <p>6 really be considered early. So I did</p> <p>7 not believe that that contributed to her</p> <p>8 risk of developing ovarian cancer.</p> <p>9 And she had menopause in her</p> <p>10 mid-50s, which is actually a little bit</p> <p>11 on the later side. So it's almost --</p> <p>12 she had a later menarche but also a</p> <p>13 later menopause, so -- but I did not</p> <p>14 feel that the interval between those two</p> <p>15 was all that significant for her -- to</p> <p>16 place her at an increased risk of</p> <p>17 developing ovarian cancer.</p> <p>18 BY MS. O'DELL:</p> <p>19 Q. And in the same way, you didn't</p> <p>20 feel her BMI was such that that was something</p> <p>21 that contributed or was a risk factor for her</p> <p>22 development of ovarian cancer. True?</p> <p>23 A. Correct.</p> <p>24 Q. You ruled that out essentially as a</p>

<p style="text-align: right;">Page 94</p> <p>1 risk factor for ovarian cancer in her case.  2 Fair?  3 MS. CURRY: Object to the form.  4 THE WITNESS: I did not believe  5 that that contributed to her risk.  6 BY MS. O'DELL:  7 Q. How many hours did you spend --  8 have you spent on Ms. Converse's case since your  9 February 2022 invoice?  10 A. Oh. So the backbone, if you will,  11 or the majority of the report was already  12 written, because I don't actually think there  13 were that many more medical records that came in  14 on her per se after the fact, so I would say  15 maybe five more hours on her case.  16 Q. I'm looking back at what we -- was  17 part of Exhibit 5 was the invoice for  18 Ms. Converse, and it indicated that you spent  19 48.25 hours in your review of her case.  20 And forgive me, would you mind  21 repeating how many hours you believe that you  22 spent on Ms. Converse's case since your February  23 2022 invoice?  24 A. Yes. I think somewhere between</p>	<p style="text-align: right;">Page 96</p> <p>1 It's -- the mean age of ovarian cancer is 63, and  2 so from that mean age, there is a bell curve out.  3 And the majority of ovarian cancers are actually  4 diagnosed, I believe, from ages 55 to like 65 or  5 66. So she's well within one standard deviation  6 of the bell curve.  7 Q. I want to look at -- well, before I  8 turn to something else, let me just ask this  9 question just to make sure I understand.  10 What are you relying on for your  11 conclusion that age is a well-established risk  12 factor that would increase Ms. Converse's risk of  13 developing clear cell ovarian cancer?  14 A. So as we just discussed, she's well  15 within one standard deviation of the mean age of  16 ovarian cancer with the majority of ovarian  17 cancers actually starting at about age 55.  18 In addition, most of societies,  19 such as ACS, SGO, OCRA, all identify age as a  20 risk factor for developing ovarian cancer.  21 In addition, you know, when you  22 look at articles that identify genetic mutations  23 and how they accumulate over the course of our  24 lifetime just from simple defects that happen as</p>
<p style="text-align: right;">Page 95</p> <p>1 five to six hours more.  2 Q. Okay. In your report for  3 Ms. Converse, Exhibit 9, you -- and page 2 is  4 where I'm looking if you want to look there.  5 I want to first focus on age. She  6 was diagnosed at age 58.  7 A. Okay.  8 Q. And, as I understand it, it's your  9 opinion that age was one of her risk factors for  10 her development of ovarian cancer, correct?  11 A. That's correct.  12 Q. And, Dr. Saenz, isn't it true that  13 the average age of the diagnosis of ovarian  14 cancer is 63?  15 A. Yes, that's correct.  16 Q. And so -- but it's your view, even  17 though the average age is 63, that her age, which  18 is five years younger than the average, would  19 still be a contributing factor to her development  20 of ovarian cancer. Is that true?  21 A. Yes, that's correct.  22 Q. And what's your -- what's your  23 basis for stating that?  24 A. So it's not actually the average.</p>	<p style="text-align: right;">Page 97</p> <p>1 a result of replication errors, the longer you're  2 alive, the more of those accumulations -- those  3 defects you accumulate. And she is well within  4 the age range of the majority of women that get  5 ovarian cancer.  6 Q. Yes, and thank you for that. I'm  7 just looking for a scientific study or reference  8 that you feel is supportive of your conclusion.  9 And I appreciate what you said about the  10 studies -- excuse me, the societies and what  11 they've said about it, but I'm really looking for  12 a reference that's published in the literature  13 that supports that conclusion.  14 A. I think you could go to --  15 MS. CURRY: Object to the form.  16 THE WITNESS: Sorry. I think  17 you could go to the Gates paper that  18 looked at age and looked specifically at  19 risk in women over 50 years old and the  20 increased risk with each year that  21 passes. I think that's actually a paper  22 that you and I have looked at together  23 before.  24 BY MS. O'DELL:</p>

<p style="text-align: right;">Page 98</p> <p>1 Q. We disagreed about that paper</p> <p>2 before --</p> <p>3 A. No.</p> <p>4 Q. -- Gates 2010?</p> <p>5 A. We had a discussion -- we had a</p> <p>6 discussion.</p> <p>7 Q. Yeah, we did.</p> <p>8 A. Maybe you remember it differently</p> <p>9 than I do, but I think we had a discussion.</p> <p>10 Q. We did have a discussion. That is</p> <p>11 true, we did.</p> <p>12 Let me -- you mentioned the</p> <p>13 societies and some of the things that the</p> <p>14 societies have said about different risk factors</p> <p>15 and symptoms of ovarian cancer.</p> <p>16 I'd like to mark the ACOG risk</p> <p>17 factors.</p> <p>18 MS. O'DELL: And if you have</p> <p>19 those, that would be great, Paula. And</p> <p>20 you may have it in the form of ACOG's</p> <p>21 FAQs.</p> <p>22 And we'll mark this as</p> <p>23 exhibit -- I believe this is Exhibit 10.</p> <p>24 (Exhibit No. 10 was marked for</p>	<p style="text-align: right;">Page 100</p> <p>1 MS. CURRY: Okay. Thank you.</p> <p>2 THE WITNESS: I don't see talc</p> <p>3 listed here in this document.</p> <p>4 BY MS. O'DELL:</p> <p>5 Q. And in terms of age, it says age</p> <p>6 older than 55. True?</p> <p>7 A. Yes.</p> <p>8 Q. And then in terms of inherited</p> <p>9 mutations, it lists mutations in BRCA1 and BRCA2</p> <p>10 genes, correct?</p> <p>11 A. Let me get there.</p> <p>12 I'm sorry, what page are you on?</p> <p>13 Q. Page 2.</p> <p>14 A. Oh, we're just looking at the list.</p> <p>15 I'm sorry. I thought we were looking at --</p> <p>16 Q. Yeah, I'm just looking at the list.</p> <p>17 A. There is -- yes, it just lists</p> <p>18 those two genes.</p> <p>19 Q. It does not list Ashkenazi Jewish</p> <p>20 heritage as a risk factor for ovarian cancer.</p> <p>21 True?</p> <p>22 A. It does not.</p> <p>23 Q. And I want to -- and I want to now</p> <p>24 mark as Exhibit 11 the SGO risk factors that you</p>
<p style="text-align: right;">Page 99</p> <p>1 identification.)</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. So, Dr. Saenz, we marked as</p> <p>4 Exhibit 10 what is an ACOG document "FAQs for</p> <p>5 Ovarian Cancer," something which you're very</p> <p>6 familiar with, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And you cite this in your report</p> <p>9 and you've testified to this a number of times at</p> <p>10 trial. True?</p> <p>11 A. I'm sure.</p> <p>12 Q. Okay. And a couple of the things</p> <p>13 that I want to point out. In terms of these risk</p> <p>14 factors and symptoms, this list that's been put</p> <p>15 forward by ACOG, it does not list talc as a risk</p> <p>16 factor. True?</p> <p>17 A. Correct.</p> <p>18 Q. And it doesn't say anything about</p> <p>19 talc. True?</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 Are you talking about this document or</p> <p>22 ACOG in general?</p> <p>23 MS. O'DELL: I think -- yeah,</p> <p>24 I'm talking about this document?</p>	<p style="text-align: right;">Page 101</p> <p>1 reference in your report.</p> <p>2 (Exhibit No. 11 was marked for</p> <p>3 identification.)</p> <p>4 MS. O'DELL: And, Paula, if you</p> <p>5 don't have it, I can put it on the</p> <p>6 screen.</p> <p>7 MS. BROWN: I have it, I think.</p> <p>8 Is this it?</p> <p>9 MS. O'DELL: Yes, that's it.</p> <p>10 Exhibit 11.</p> <p>11 BY MS. O'DELL:</p> <p>12 Q. And you recognize this as the SGO</p> <p>13 list of risk factors for ovarian cancer. True?</p> <p>14 A. Yes.</p> <p>15 Q. And if you look on page 1 of the</p> <p>16 document, it lists women with BRCA1 or 2</p> <p>17 mutation.</p> <p>18 A. True.</p> <p>19 Q. True?</p> <p>20 A. Correct.</p> <p>21 Q. And it does not list women with</p> <p>22 Ashkenazi Jewish heritage. True?</p> <p>23 A. It does not.</p> <p>24 Q. And we can agree, can't we,</p>



<p style="text-align: right;">Page 102</p> <p>1 Dr. Saenz, that Ms. Converse tested negative for</p> <p>2 BRCA1 and 2?</p> <p>3 A. Yes, she did.</p> <p>4 Q. And in the broader testing that</p> <p>5 Ms. Converse had, she tested negative for all the</p> <p>6 known pathogenic genes for ovarian cancer,</p> <p>7 correct?</p> <p>8 MS. CURRY: Object to the form.</p> <p>9 THE WITNESS: So she tested</p> <p>10 positive for two VUSes. One was in ATM,</p> <p>11 and those were the same two mutations</p> <p>12 that her mom had as well. The VUS that</p> <p>13 she had in ATM is thought to be</p> <p>14 pathogenic but perhaps not deleterious.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. In terms of no pathogenic</p> <p>17 deleterious gene mutations, inherited mutations,</p> <p>18 Ms. Converse tested negative to all of those</p> <p>19 genes. True?</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 THE WITNESS: No, that's not</p> <p>22 true, because pathogenic and deleterious</p> <p>23 don't necessarily mean the same thing.</p> <p>24 BY MS. O'DELL:</p>	<p style="text-align: right;">Page 104</p> <p>1 Q. Looking at Exhibit 11, the SGO</p> <p>2 ovarian cancer risk factors, this document does</p> <p>3 not list or refer to talc, correct?</p> <p>4 A. It does not.</p> <p>5 Q. In relation to -- if you wouldn't</p> <p>6 mind, I want to ask you some more questions about</p> <p>7 your report, but if you'll keep the list of risk</p> <p>8 factors handy, I want to ask you some -- I want</p> <p>9 to go back to them at various points.</p> <p>10 Looking at your discussion of</p> <p>11 Ms. Converse, regarding her Ashkenazi Jewish</p> <p>12 heritage on page 5 of your case-specific</p> <p>13 report -- do you see that, page 5, about midway</p> <p>14 through the middle paragraph?</p> <p>15 A. Yes.</p> <p>16 Q. And you write: "Being of Ashkenazi</p> <p>17 Jewish" -- excuse me, "Being of Ashkenazi</p> <p>18 heritage also increased Ms. Converse's risk of</p> <p>19 developing ovarian cancer, regardless of her past</p> <p>20 genetic testing."</p> <p>21 And then you go on to cite</p> <p>22 Crawford, et al., 2017, and state: "Crawford,</p> <p>23 et al., 2017, reported on women previously found</p> <p>24 to be negative for mutations in BRCA1 and 2."</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. I understand.</p> <p>2 A. So the variant that she has in ATM</p> <p>3 has not -- as we sit here, has not been directly</p> <p>4 linked to ovarian cancer, in that you are</p> <p>5 correct, but she does have that mutation.</p> <p>6 Q. I understand.</p> <p>7 But in terms of known genes -- not</p> <p>8 anticipated, not suspicious, not could be proven</p> <p>9 in the future -- in terms of known genes that</p> <p>10 are -- have been established to increase the risk</p> <p>11 of ovarian cancer, Ms. Converse's testing was</p> <p>12 negative. True?</p> <p>13 MS. CURRY: Object to the form.</p> <p>14 THE WITNESS: That is true. But</p> <p>15 the genetics counselors that counseled</p> <p>16 her were still extremely worried about</p> <p>17 her and her risk of breast cancer, and</p> <p>18 her daughter's risk, based on her family</p> <p>19 history and based on the fact that</p> <p>20 genetic testing was not entirely normal,</p> <p>21 and that is the reason that they put her</p> <p>22 in a high risk breast cancer screening</p> <p>23 clinic.</p> <p>24 BY MS. O'DELL:</p>	<p style="text-align: right;">Page 105</p> <p>1 Do you see where I'm reading?</p> <p>2 A. Yes, ma'am.</p> <p>3 Q. And did I represent that correctly?</p> <p>4 A. Yes.</p> <p>5 Q. And do you agree, Dr. Saenz, that</p> <p>6 women who have a personal or family history of</p> <p>7 breast cancer or ovarian cancer but who do not</p> <p>8 have a documented BRCA1, 2, or other hereditary</p> <p>9 breast or ovarian cancers associated gene should</p> <p>10 be managed based on their family history? Do you</p> <p>11 agree with that?</p> <p>12 A. In certain circumstances, yes.</p> <p>13 Q. And do you agree or disagree with</p> <p>14 the statement that preliminary data have</p> <p>15 suggested that women from families with a history</p> <p>16 of breast cancer -- excuse me -- of only breast</p> <p>17 cancer but not ovarian cancer, in which no BRCA</p> <p>18 mutation is identified, remained at a</p> <p>19 significantly increased risk of breast cancer but</p> <p>20 not ovarian cancer?</p> <p>21 A. I'm sorry, I got lost in there.</p> <p>22 MS. CURRY: Where are you</p> <p>23 reading from?</p> <p>24 MS. O'DELL: I'm reading from my</p>

<p style="text-align: right;">Page 106</p> <p>1 notes, so -- but --</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. So --</p> <p>4 A. I'm sorry, because I think we</p> <p>5 tripped over breast and ovary a couple of times,</p> <p>6 and so I lost -- I got lost in there.</p> <p>7 Q. Okay. Let me try again.</p> <p>8 Do you agree or disagree with this</p> <p>9 statement: Preliminary data have suggested that</p> <p>10 women from families with a history of only breast</p> <p>11 cancer --</p> <p>12 Are you with me, only breast</p> <p>13 cancer?</p> <p>14 A. Yes, I'm with you.</p> <p>15 Q. -- but not ovarian cancer, in which</p> <p>16 no BRCA mutation is identified, remain at a</p> <p>17 significantly increased risk of breast cancer but</p> <p>18 not ovarian cancer? Do you agree or disagree</p> <p>19 with that statement?</p> <p>20 A. I disagree with that statement.</p> <p>21 Q. Why?</p> <p>22 A. Because we know that women who have</p> <p>23 a family history of breast cancer, particularly</p> <p>24 in a first-degree relative who had their breast</p>	<p style="text-align: right;">Page 108</p> <p>1 looked at so far has put together their own</p> <p>2 listing of risk factors, and although there's</p> <p>3 significant overlap between the two, there are</p> <p>4 variances within them.</p> <p>5 Q. And if -- assume for me that ACOG</p> <p>6 and SGO have said that women with a history of</p> <p>7 only breast cancer, BRCA negative, that they are</p> <p>8 at a significantly increased risk of breast</p> <p>9 cancer but not ovarian cancer, assume for me that</p> <p>10 that's correct -- and I'll represent that that is</p> <p>11 correct that ACOG and SGO have made those</p> <p>12 statements -- if that's true, you would disagree</p> <p>13 with ACOG and SGO, and follow the NCCN</p> <p>14 guidelines. Is that your testimony?</p> <p>15 MS. CURRY: Object to the form.</p> <p>16 THE WITNESS: Your assumption is</p> <p>17 incorrect, though, because I'm actually</p> <p>18 looking at the SGO risk factors, and it</p> <p>19 says women who have a strong family</p> <p>20 history of breast or ovarian. So SGO</p> <p>21 has not said not breast.</p> <p>22 BY MS. O'DELL:</p> <p>23 Q. I mean, I'm talking about in terms</p> <p>24 of a woman who has a family member with breast</p>
<p style="text-align: right;">Page 107</p> <p>1 cancer at less than 50 years old, are at a 3 to 5</p> <p>2 times -- sorry, 3 to 5 percent risk of developing</p> <p>3 ovarian cancer. So it's about 3 to -- a</p> <p>4 threefold increased risk of developing ovarian</p> <p>5 cancer just with one first-degree relative, and</p> <p>6 in particular if that breast cancer occurred at</p> <p>7 less than 50 years old.</p> <p>8 Q. What are you basing that on? Is</p> <p>9 there a reference or study that you're relying on</p> <p>10 in making that statement?</p> <p>11 A. Can I go to my general report?</p> <p>12 Q. Yeah, sure.</p> <p>13 A. Okay. So in my general report, it</p> <p>14 would be the Hall 2001 study. Sorry, that's the</p> <p>15 primary one. Sorry, that's if they themselves</p> <p>16 had cancer before.</p> <p>17 But there's also NCCN guidelines</p> <p>18 2024.</p> <p>19 Q. And if the NCCN guidelines disagree</p> <p>20 with statements by ACOG and SGO, it's your view</p> <p>21 that they would be incorrect?</p> <p>22 A. I don't know what you're</p> <p>23 referencing, and I wouldn't say that. I mean,</p> <p>24 it's my view that every organization that we've</p>	<p style="text-align: right;">Page 109</p> <p>1 cancer, negative for BRCA testing, that person is</p> <p>2 at increased risk for breast cancer but not</p> <p>3 ovarian cancer. That's the statement that we're</p> <p>4 discussing.</p> <p>5 A. And that statement is incorrect.</p> <p>6 That's not listed on the SGO risk factors in the</p> <p>7 way that you're stating that.</p> <p>8 Q. Do you disagree that most cases of</p> <p>9 inherited predisposition to ovarian cancer are</p> <p>10 caused by pathogenic variance in BRCA1, BRCA2 or</p> <p>11 other hereditary breast and ovarian cancer</p> <p>12 associated genes?</p> <p>13 MS. CURRY: Object to the form.</p> <p>14 THE WITNESS: So I wouldn't say</p> <p>15 cause for anything. Again, I don't know</p> <p>16 what causes cancer in any individual</p> <p>17 woman because, as we've discussed</p> <p>18 before, you can have one of those</p> <p>19 pathogenic variants and never actually</p> <p>20 get cancer.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. Okay. Do you -- and I believe we</p> <p>23 established this before, so -- we did, we talked</p> <p>24 about this a minute ago, so I'm not going to</p>



<p style="text-align: right;">Page 110</p> <p>1 rehash that.</p> <p>2 Let's me just -- let's focus in on</p> <p>3 Ashkenazi Jewish heritage. Do you agree that</p> <p>4 most of the increased risk of ovarian cancer</p> <p>5 among women who are of Ashkenazi Jewish descent</p> <p>6 is accounted for by inherited mutations in BRCA1</p> <p>7 or 2?</p> <p>8 MS. CURRY: Object to the form.</p> <p>9 THE WITNESS: I think that's</p> <p>10 true. I think the majority are, but</p> <p>11 there's still a certain percentage of</p> <p>12 women that are Ashkenazi that don't have</p> <p>13 identified mutations in those genes that</p> <p>14 still seem to be at an increased risk of</p> <p>15 developing ovarian cancer, and we</p> <p>16 don't --</p> <p>17 BY MS. O'DELL:</p> <p>18 Q. And -- I'm sorry.</p> <p>19 A. No, it's okay.</p> <p>20 -- we don't necessarily know why</p> <p>21 that is. We've just seen that.</p> <p>22 Q. But even for women who are</p> <p>23 Ashkenazi Jewish descent and maybe even BRCA1 and</p> <p>24 2 positive, they're also susceptible to other</p>	<p style="text-align: right;">Page 112</p> <p>1 MS. CURRY: Object to the form.</p> <p>2 THE WITNESS: So, in particular,</p> <p>3 I think about things such as dietary</p> <p>4 interventions, essentially -- like a</p> <p>5 lifestyle intervention, if you will.</p> <p>6 But I'm unaware of any -- at</p> <p>7 least for the serous histologies, I'm</p> <p>8 unaware of any environmental factor</p> <p>9 increasing the risk of developing</p> <p>10 ovarian cancer. I mean, I would modify</p> <p>11 my answer a little bit to say that there</p> <p>12 is some literature that smoking</p> <p>13 increases the risk of the development of</p> <p>14 mucinous ovarian cancer, but I think</p> <p>15 that's the only environmental risk</p> <p>16 factor for which there's been somewhat</p> <p>17 consistent literature in increasing the</p> <p>18 risk of developing a form of ovarian</p> <p>19 cancer.</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. So I want to turn now to the</p> <p>22 article you cite, the Crawford article, and mark</p> <p>23 that as Exhibit 12.</p> <p>24 (Exhibit No. 12 was marked for</p>
<p style="text-align: right;">Page 111</p> <p>1 somatic mutations that can contribute to their</p> <p>2 development of ovarian cancer. True?</p> <p>3 A. We all are. If you have ovaries,</p> <p>4 you're at risk.</p> <p>5 Q. And so they would be susceptible</p> <p>6 just like anyone else to reproductive risk</p> <p>7 factors, for example?</p> <p>8 A. They would be at risk for those</p> <p>9 risk factors contributing to their development of</p> <p>10 the disease, correct.</p> <p>11 Q. And they would be susceptible to</p> <p>12 environmental risk factors for ovarian cancer as</p> <p>13 well. True?</p> <p>14 MS. CURRY: Object to the form.</p> <p>15 THE WITNESS: So I don't</p> <p>16 necessarily know what you mean by</p> <p>17 "environmental," and in fact, I'm</p> <p>18 unaware of any environmental risk</p> <p>19 factors increasing the risk of ovarian</p> <p>20 cancer.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. And how about your understanding,</p> <p>23 what's your framework when you're thinking about</p> <p>24 an environmental risk factor?</p>	<p style="text-align: right;">Page 113</p> <p>1 identification.)</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. It's Crawford 2017.</p> <p>4 And let me know when you have it.</p> <p>5 A. I will.</p> <p>6 Q. Okay. Thank you.</p> <p>7 MS. O'DELL: Is it in there,</p> <p>8 Paula?</p> <p>9 MS. BROWN: I don't see it in</p> <p>10 here, Leigh.</p> <p>11 MS. O'DELL: I'm sorry?</p> <p>12 THE WITNESS: She doesn't have</p> <p>13 it.</p> <p>14 MS. BROWN: Yeah, I don't have</p> <p>15 it in here.</p> <p>16 MS. O'DELL: All right. No</p> <p>17 problem.</p> <p>18 BY MS. O'DELL:</p> <p>19 Q. Let me just pull that up.</p> <p>20 I'll share my screen, and I'm also</p> <p>21 going to put it in the chat so you can have</p> <p>22 access to it, Dr. Saenz.</p> <p>23 A. Thank you.</p> <p>24 Q. It should be in the chat now.</p>

<p style="text-align: right;">Page 114</p> <p>1 THE WITNESS: Do you have it?</p> <p>2 MS. CURRY: I don't see it in</p> <p>3 the chat.</p> <p>4 Do you know how to pull that up</p> <p>5 on here? I'm not seeing it on -- like a</p> <p>6 function on her.</p> <p>7 MS. BROWN: Yeah, she can't look</p> <p>8 at you and look at the document, so</p> <p>9 she's just looking at the document, but</p> <p>10 she's still with us.</p> <p>11 MS. O'DELL: Okay.</p> <p>12 THE WITNESS: I'm still here.</p> <p>13 BY MS. O'DELL:</p> <p>14 Q. All right. Good. Well, thanks for</p> <p>15 doing that.</p> <p>16 So this is the Crawford 2017</p> <p>17 article you cite in your report. True?</p> <p>18 A. Let me just take a quick look at</p> <p>19 it. (Peruses document.)</p> <p>20 I believe so, yep.</p> <p>21 Q. And if you'll look -- and I'll just</p> <p>22 for ease just point you to the abstract and the</p> <p>23 methods. They tested 300 women in this study</p> <p>24 with a multigene panel. True?</p>	<p style="text-align: right;">Page 116</p> <p>1 personal history of breast cancer or a first- or</p> <p>2 second-degree relative with ovarian cancer.</p> <p>3 True?</p> <p>4 A. Correct.</p> <p>5 Q. And she did have ovarian cancer.</p> <p>6 A. Correct.</p> <p>7 Q. And in addition to BRCA1 and 2</p> <p>8 testing for Ms. Converse, she also had full</p> <p>9 sequencing testing of BRCA1 and 2. True?</p> <p>10 A. Yes.</p> <p>11 Q. And the patients in the Crawford</p> <p>12 study did not have full sequencing testing of</p> <p>13 BRCA1 and 2. Correct?</p> <p>14 A. They -- they tested negative --</p> <p>15 they had comprehensive sequencing, they could</p> <p>16 have. Some of them had limited, but some of them</p> <p>17 had comprehensive sequencing.</p> <p>18 Q. It wasn't a criteria of the study,</p> <p>19 was it, so that everyone had to have</p> <p>20 comprehensive testing, correct?</p> <p>21 A. The patients in the study had</p> <p>22 either limited or comprehensive, so both were</p> <p>23 allowed in.</p> <p>24 Q. And in Ms. Converse's case, and --</p>
<p style="text-align: right;">Page 115</p> <p>1 A. Yes.</p> <p>2 Q. And part of the criteria for their</p> <p>3 participation in this study was that they tested</p> <p>4 negative for BRCA1 and 2, correct?</p> <p>5 A. In the past.</p> <p>6 Q. Yes. They've been tested for BRCA1</p> <p>7 and 2, and it was negative.</p> <p>8 A. Correct.</p> <p>9 Q. And they also met one of the other</p> <p>10 following criteria, and so they either -- they</p> <p>11 met, one, personal history of bilateral breast</p> <p>12 cancer. True?</p> <p>13 A. Yes.</p> <p>14 Q. That was one of the criteria.</p> <p>15 A. Mm-hmm.</p> <p>16 Q. And Ms. Converse does not have a</p> <p>17 personal history of breast cancer, correct?</p> <p>18 A. Correct.</p> <p>19 Q. The second -- and a personal</p> <p>20 history of breast cancer or a -- and, excuse me,</p> <p>21 a first- or second-degree relative with ovarian</p> <p>22 cancer. That was the second criteria, right?</p> <p>23 A. Yes.</p> <p>24 Q. And Ms. Converse neither has a</p>	<p style="text-align: right;">Page 117</p> <p>1 she had additional testing beyond BRCA1 and 2 in</p> <p>2 2014, correct?</p> <p>3 A. She had additional testing of 20</p> <p>4 other genes, and that's when those two VUSes were</p> <p>5 discovered, correct.</p> <p>6 Q. And in that testing where she had,</p> <p>7 you know, the additional testing in 2014, she</p> <p>8 had, I think you mentioned, 20 additional genes</p> <p>9 tested. True?</p> <p>10 A. That's what -- that's what the</p> <p>11 genetics report said, yes.</p> <p>12 Q. And in the genetics report, she</p> <p>13 had -- no mutations were noted. True?</p> <p>14 MS. CURRY: Object to the form.</p> <p>15 THE WITNESS: No, that's not</p> <p>16 true, because those two VUSes were</p> <p>17 identified.</p> <p>18 BY MS. O'DELL:</p> <p>19 Q. And did the women in the Crawford</p> <p>20 study have a multigene panel as a part of the</p> <p>21 testing process?</p> <p>22 MS. CURRY: Object to the form,</p> <p>23 asked and answered.</p> <p>24 THE WITNESS: Yes.</p>

<p style="text-align: right;">Page 118</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. Can you show me where it says that</p> <p>3 in your paper?</p> <p>4 A. That the women in the study had</p> <p>5 testing?</p> <p>6 Q. Yeah -- no, no, no. A multigene</p> <p>7 panel -- not just BRCA1 and 2 testing but a</p> <p>8 multigene panel of all the genes associated with</p> <p>9 ovarian cancer.</p> <p>10 A. That's what this study is. It's on</p> <p>11 page 3 of 8, multigene panel validation, and --</p> <p>12 Q. Yes.</p> <p>13 A. -- they looked at --</p> <p>14 Q. I'm asking an inartful question. I</p> <p>15 apologize.</p> <p>16 They did not have the range of</p> <p>17 testing that covered as many genes as</p> <p>18 Ms. Converse, did they?</p> <p>19 MS. CURRY: Object to the form.</p> <p>20 THE WITNESS: I don't actually</p> <p>21 understand what you're asking me. What</p> <p>22 this study looked at was comprehensive</p> <p>23 screening of other genes.</p> <p>24 BY MS. O'DELL:</p>	<p style="text-align: right;">Page 120</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. If you're there.</p> <p>3 A. I'm there.</p> <p>4 Q. It says: "Ashkenazi Jewish women</p> <p>5 had elevated pathogenic mutation rates of 12</p> <p>6 percent over -- 12 percent over other</p> <p>7 ethnicities."</p> <p>8 Do you see where I'm reading?</p> <p>9 A. Yes.</p> <p>10 Q. Do you take that from Crawford as</p> <p>11 well, that 12 percent?</p> <p>12 A. That is from Crawford.</p> <p>13 Q. And this 12 percent that you're</p> <p>14 talking about is for women other than those who</p> <p>15 test negative for pathogenic mutations, correct?</p> <p>16 A. I'm not --</p> <p>17 Q. Twelve percent does not refer to</p> <p>18 women like Ms. Converse who tested negative for</p> <p>19 a -- not only for BRCA1 and 2 but an expanded</p> <p>20 panel of pathogenic genes. Correct?</p> <p>21 MS. CURRY: Object to the form.</p> <p>22 THE WITNESS: I'm not following</p> <p>23 you. I'm sorry. I'm --</p> <p>24 BY MS. O'DELL:</p>
<p style="text-align: right;">Page 119</p> <p>1 Q. Right. But I guess -- I'm sorry,</p> <p>2 I'm asking it poorly and I apologize, but she --</p> <p>3 Ms. Converse had a broader panel of testing than</p> <p>4 the women in the Crawford study, correct?</p> <p>5 MS. CURRY: Object to the form.</p> <p>6 THE WITNESS: I don't think</p> <p>7 that's the case, because that was the</p> <p>8 point of what these authors were doing.</p> <p>9 BY MS. O'DELL:</p> <p>10 Q. Let me -- I mean, I don't want to</p> <p>11 belabor it, so let me just -- in -- in your</p> <p>12 report, you say -- I'm back on page 9 of your</p> <p>13 Converse case-specific report, Exhibit 9, and it</p> <p>14 says: "Ashkenazi Jewish women have elevated</p> <p>15 pathogenic mutation" --</p> <p>16 A. I'm sorry, Ms. O'Dell, at page 9?</p> <p>17 Q. I'm sorry. Page 5 of Exhibit 9.</p> <p>18 That's what I was trying to say, page 5 of</p> <p>19 Exhibit 9, your case-specific report.</p> <p>20 A. Okay. I am now on page 5. And you</p> <p>21 are --</p> <p>22 MS. CURRY: Can you repeat what</p> <p>23 you were reading?</p> <p>24 MS. O'DELL: Yeah.</p>	<p style="text-align: right;">Page 121</p> <p>1 Q. Okay. I think -- you know, I guess</p> <p>2 in terms of --</p> <p>3 A. I mean, I can -- okay. Sorry, go</p> <p>4 right ahead. I'm sorry. I'll wait for your</p> <p>5 question. I apologize.</p> <p>6 Q. What were you going to say?</p> <p>7 A. That the 12 percent comes from</p> <p>8 Table 5.</p> <p>9 Q. Okay. I'm there.</p> <p>10 A. Okay. So the total of Ashkenazi</p> <p>11 women, the percent that tested positive for</p> <p>12 mutation that previously tested negative was 12</p> <p>13 percent. Line 2 in the table, Ashkenazi women.</p> <p>14 So that was --</p> <p>15 Q. But she -- I guess this is -- we're</p> <p>16 getting at it now. This is the confusion.</p> <p>17 So you're saying this paper is</p> <p>18 saying that 12 percent that previously tested for</p> <p>19 BRCA1 and 2 is negative, had a broader panel, and</p> <p>20 they then tested positive for a gene on the</p> <p>21 broader panel. That's the finding of Crawford,</p> <p>22 correct?</p> <p>23 A. Or a mutation that was previously</p> <p>24 missed in BRCA1 and 2, that's correct.</p>

<p style="text-align: right;">Page 122</p> <p>1 Q. Okay. That's correct. And in 2 Ms. Converse's case, she tested negative for 3 BRCA1 and 2. She -- she then tested a broader 4 gene panel, and she was negative for all the 5 genes on that broader panel, correct? 6 MS. CURRY: Object to the form. 7 THE WITNESS: No, that's not 8 correct, because she had mutations in 9 ATM and I think it was TGF beta-2. And 10 they were VUSes, but they were still 11 mutations. 12 BY MS. O'DELL: 13 Q. Okay. She -- okay. Fair enough. 14 Let's -- but let's -- the VUSes are variants of 15 unknown significance, correct? 16 A. Or uncertain significance. Both 17 terminologies are used, correct. 18 Q. And so for those genes that are of 19 known significance, known to -- and accepted they 20 increase the risk of ovarian cancer, she tested 21 negative. True? 22 A. I don't -- I would never phrase it 23 that way, because those genes that she did have 24 mutations in were VUSes, which means they have</p>	<p style="text-align: right;">Page 124</p> <p>1 cancer. True? 2 A. It's my opinion that she had 3 endometriosis, and we know that endometriosis can 4 increase your risk of developing ovarian cancer. 5 Q. But in your opinion, it's not 6 causal. It just increased her risk, correct? 7 A. I do not know what causes ovarian 8 cancer in any one particular woman. 9 I'm sorry, Ms. O'Dell, can I 10 interrupt you for one second? I apologize. In 11 my review last evening of this report, I saw that 12 I had somehow glitched a portion of a sentence 13 out, and so it doesn't even make sense as a 14 sentence. And I want to bring that to your 15 attention because it's incorrect. 16 So at the very top -- 17 Q. Where is it? 18 A. Page 8, the very top, since we're 19 on the endometriosis section. 20 It says: "Dr. Schwartz," comma, 21 "Ms. Converse's background." That's not a full 22 sentence. That's not good English and it doesn't 23 make sense. That -- I don't know how I cut that 24 out, but what that did and should say, and we can</p>
<p style="text-align: right;">Page 123</p> <p>1 yet to be identified as deleterious, but we don't 2 actually -- you can't say they are not cancer 3 causing. 4 Q. Let me ask it differently. 5 A. Okay. 6 Q. She tested negative to every known 7 gene that is established to increase the risk of 8 ovarian cancer. True? 9 MS. CURRY: Object to the form. 10 THE WITNESS: In the panel that 11 she was tested on at the time in 2014. 12 BY MS. O'DELL: 13 Q. That's true? 14 A. I will agree with that, with the 15 addition of what I just said. 16 Q. Okay. Let's turn to endometriosis. 17 A. Should we come out of the chat 18 of this paper? 19 Q. Yes, please. Thank you. You can 20 take that off the screen. 21 A. Okay. 22 Q. So it's your opinion that 23 endometriosis is a likely substantial 24 contributing factor to Ms. Converse's clear cell</p>	<p style="text-align: right;">Page 125</p> <p>1 supply to you later, is: "Dr. Schwartz, 2 Ms. Converse's gynecologic oncologist, stated in 3 deposition that he believes that Ms. Converse's 4 cancer arose in an endometriosis background." 5 And the reference there from his 6 deposition testimony is correct, but somehow I 7 butchered that sentence. I apologize. 8 It's not dissimilar from on page 6, 9 where I actually say: "As stated above, 10 Dr. Schwartz, Ms. Converse's gynecologic 11 oncologist, believes that her cancer likely arose 12 in a background of endometriosis." 13 I think I may have moved that 14 sentence at one point to another place, and 15 that's what happened. 16 MS. CURRY: We can supply a new 17 report with the language put back in 18 there. I think it was just like a half 19 a sentence that somehow got cut out, but 20 the -- it references still that what 21 she's referring to still is there in 22 footnote 34. 23 THE WITNESS: It didn't -- I 24 don't think it belonged on page 6. I</p>

<p style="text-align: right;">Page 126</p> <p>1 think I accidentally cut and pasted it</p> <p>2 there and spliced it out. So, sorry.</p> <p>3 BY MS. O'DELL:</p> <p>4 Q. Okay. And you planned to say that</p> <p>5 Dr. Schwartz, Ms. Converse's GYN oncologist</p> <p>6 stated that her clear cell ovarian cancer arose</p> <p>7 in an endometriosis background. That's the</p> <p>8 addition?</p> <p>9 A. Yes, ma'am.</p> <p>10 Q. Would you agree with me, Dr. Saenz,</p> <p>11 that there's no mention of endometriosis in</p> <p>12 Ms. Converse's medical records?</p> <p>13 A. I actually don't think that's true,</p> <p>14 because Dr. Schwartz's op note discusses that the</p> <p>15 mass was adherent to some degree, and there was</p> <p>16 extrusion of green fluid from intraoperative</p> <p>17 rupture of the mass, and that's consistent with</p> <p>18 endometriosis, and actually the green fluid most</p> <p>19 likely is old blood and hemosiderin products</p> <p>20 that -- from the old blood in an endometrioma.</p> <p>21 Q. Let me be more clear.</p> <p>22 In the pathology report,</p> <p>23 Ms. Converse's surgical procedure, and the date</p> <p>24 of the report is September 10th, 2007 --</p>	<p style="text-align: right;">Page 128</p> <p>1 MS. BROWN: Yes.</p> <p>2 MS. O'DELL: So Exhibit 13,</p> <p>3 it's -- Paula, it's the key medical</p> <p>4 records pathology. And if you don't</p> <p>5 have it, I can pull it up for Dr. Saenz.</p> <p>6 It's Converse HYCCMR00223</p> <p>7 through 226.</p> <p>8 MS. BROWN: The ones I have are</p> <p>9 not Bates stamped.</p> <p>10 MS. O'DELL: Okay. It's -- I</p> <p>11 don't know if you can -- if this helps</p> <p>12 you, but it looks like that</p> <p>13 (indicating).</p> <p>14 I don't know if that helps or</p> <p>15 not.</p> <p>16 MS. BROWN: Yes. This looks</p> <p>17 like it. Is that it?</p> <p>18 THE WITNESS: It should be</p> <p>19 September 5th.</p> <p>20 MS. CURRY: Yeah. Do you want</p> <p>21 to mark it?</p> <p>22 MS. BROWN: We got it.</p> <p>23 (Exhibit No. 13 was marked for</p> <p>24 identification.)</p>
<p style="text-align: right;">Page 127</p> <p>1 A. The pathology.</p> <p>2 Q. Correct.</p> <p>3 A. Okay.</p> <p>4 Q. The pathology report does not</p> <p>5 contain a finding of endometriosis. True?</p> <p>6 A. They do not specify that, but as</p> <p>7 Dr. Schwartz said, the initial frozen section was</p> <p>8 that the cancer was an endometrioid cancer, but</p> <p>9 the final path was clear cell. And even</p> <p>10 Dr. Schwartz interpreted that, because they</p> <p>11 initially looked at it and thought they were</p> <p>12 looking at an endometrioid cancer, but it</p> <p>13 ultimately was clear cell. That's why he said</p> <p>14 that this tumor arose in an endometrioid</p> <p>15 background. So that the changing --</p> <p>16 Q. Let me -- I'm sorry.</p> <p>17 A. -- the changing of the histology on</p> <p>18 the path report from the frozen to the permanent</p> <p>19 is consistent with endometriosis.</p> <p>20 Q. And I just -- and I'm happy to mark</p> <p>21 this pathology report. It's -- and I will go</p> <p>22 ahead and mark it just so there's clarity.</p> <p>23 MS. O'DELL: And I was on</p> <p>24 Exhibit 13?</p>	<p style="text-align: right;">Page 129</p> <p>1 MS. O'DELL: Okay, thank you.</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. Exhibit 13. And this is the</p> <p>4 pathology report from Ms. Converse's surgical</p> <p>5 procedure after her diagnosis or at the time of</p> <p>6 her diagnosis, and does this pathology report</p> <p>7 contain a diagnosis or an identification of</p> <p>8 endometriosis?</p> <p>9 A. It doesn't mention it one way or</p> <p>10 another, but the frozen section was initially</p> <p>11 interpreted as --</p> <p>12 I don't know where you went, Leigh.</p> <p>13 I lost you. I don't know who I'm looking at.</p> <p>14 Q. I'm right here.</p> <p>15 A. Oh, okay, you're back.</p> <p>16 We were looking at something else.</p> <p>17 I don't know what.</p> <p>18 MS. CURRY: Yeah, that was</p> <p>19 weird.</p> <p>20 THE WITNESS: The frozen</p> <p>21 section --</p> <p>22 MS. O'DELL: I've not moved. I</p> <p>23 represent that for the record. I'm</p> <p>24 sitting right here, so I don't know what</p>



<p style="text-align: right;">Page 130</p> <p>1 that was.</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. But just so I understand, the</p> <p>4 pathology report itself that I have marked as</p> <p>5 Exhibit 13 does not contain a diagnosis of -- or</p> <p>6 identification of endometriosis, correct?</p> <p>7 A. It does not identify -- it doesn't</p> <p>8 mention its absence or its presence.</p> <p>9 Q. And you talked about this reference</p> <p>10 to intraoperative leakage of green fluid in the</p> <p>11 operative report. You mentioned that a few</p> <p>12 minutes ago. And you -- you suggest that that</p> <p>13 means that there was the presence of</p> <p>14 endometriosis.</p> <p>15 Is it also true that it could not</p> <p>16 be endometriosis?</p> <p>17 A. I don't think that's the case. I</p> <p>18 don't know what else would be green fluid other</p> <p>19 than hemosiderin.</p> <p>20 Q. Masses can be injured during</p> <p>21 surgery and the contents of the mass extruded</p> <p>22 without there being any presence of</p> <p>23 endometriosis. True?</p> <p>24 MS. CURRY: Object to the form.</p>	<p style="text-align: right;">Page 132</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. If you -- did you look at</p> <p>3 Dr. Godleski's plaintiffs' experts -- expert</p> <p>4 pathologist's review of Ms. Converse's pathology</p> <p>5 materials?</p> <p>6 A. I did.</p> <p>7 Q. And is it your opinion that</p> <p>8 Dr. Godleski did not examine the pathology</p> <p>9 materials for the presence of endometriosis?</p> <p>10 A. I do not believe that Dr. Godleski</p> <p>11 indicated one way or another whether or not</p> <p>12 endometriosis was present.</p> <p>13 Q. Pathologists by sort of methodology</p> <p>14 only identify things -- they only note, I should</p> <p>15 say, in their reports things they see on</p> <p>16 pathology. True? I mean, that's the general</p> <p>17 practice of a pathologist. Would you agree with</p> <p>18 me on that?</p> <p>19 MS. CURRY: Object to the form.</p> <p>20 THE WITNESS: No.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. So, for example, a pathologist</p> <p>23 doesn't look at a specimen and say all the things</p> <p>24 they don't see. They identify what they do see.</p>
<p style="text-align: right;">Page 131</p> <p>1 THE WITNESS: Right, but here</p> <p>2 there was extrusion of green fluid,</p> <p>3 which is hemosiderin.</p> <p>4 BY MS. O'DELL:</p> <p>5 Q. Is there any medical record in Dr.</p> <p>6 -- in the hospitalization of Ms. Converse or even</p> <p>7 Dr. Schwartz's own records from his clinic, is</p> <p>8 there any medical record that describes her tumor</p> <p>9 as arising from endometriosis?</p> <p>10 A. There's Dr. Schwartz's testimony.</p> <p>11 Q. No, no, please, I'm asking about a</p> <p>12 medical record.</p> <p>13 A. I did not see a medical record.</p> <p>14 Q. You marked it --</p> <p>15 THE WITNESS: So, Margaret --</p> <p>16 I'm sorry, Leigh, Margaret keeps coming</p> <p>17 in and out of our screens. I don't know</p> <p>18 why. I think that's where I'm losing</p> <p>19 you.</p> <p>20 MS. O'DELL: Hey, Margaret, do</p> <p>21 you mind just either --</p> <p>22 MS. THOMPSON: Yeah, sorry. I</p> <p>23 will turn off my camera.</p> <p>24 MS. O'DELL: Okay.</p>	<p style="text-align: right;">Page 133</p> <p>1 They're not going to look at in an ovarian cancer</p> <p>2 case pathology materials from the cervix and note</p> <p>3 there was no cervical cancer. True? They</p> <p>4 just --</p> <p>5 A. I don't agree -- I don't agree with</p> <p>6 you there, because there are times, even in this</p> <p>7 pathology report, and I call your attention back</p> <p>8 to specimen 13, where they're looking at the</p> <p>9 other biopsies that were taken, and they say</p> <p>10 negative for carcinoma.</p> <p>11 So I think it depends upon the</p> <p>12 charge that they are given what they identify and</p> <p>13 don't identify. So even in this pathology report</p> <p>14 on Ms. Converse from Yale, they say negative for</p> <p>15 carcinoma. So I can't agree with you.</p> <p>16 I don't know why Dr. Godleski did</p> <p>17 not mention the endometriosis that was there, and</p> <p>18 Dr. Felix identified it, and so did Dr. Schwartz</p> <p>19 in his deposition testimony.</p> <p>20 Q. Dr. Godleski testified to a</p> <p>21 reasonable degree of scientific and medical</p> <p>22 certainty that endometriosis was not present.</p> <p>23 Are you aware of that?</p> <p>24 A. I have not seen that testimony.</p>

<p style="text-align: right;">Page 134</p> <p>1 Q. Let's talk about your discussion in 2 relation to the studies and endometriosis. We'll 3 move on from the medical records to the studies 4 themselves. 5 And I'll ask you to turn to page 10 6 of your case-specific report. 7 A. Okay. 8 Q. And you list studies that -- you 9 list Terry as showing a statistically significant 10 increased risk with genital talc and clear cell 11 carcinoma on page 10, and you list some other 12 studies as well that you view as not supporting a 13 relationship between clear cell and ovarian 14 cancer in the table. Correct? 15 MS. CURRY: Object to the form. 16 THE WITNESS: So I'm not viewing 17 anything here. I'm simply listing the 18 nine studies that have examined whether 19 or not there is a specific histologic 20 analysis in breaking down cases in 21 particular with respect to clear cell 22 carcinoma and the perineal application 23 of talc. 24 BY MS. O'DELL:</p>	<p style="text-align: right;">Page 136</p> <p>1 cell histology, on the studies that looked 2 specifically at clear cell. 3 Q. And we agree, I believe, that clear 4 cell carcinoma would be in that category of 5 nonserous ovarian cancers. True? 6 A. That's -- correct, it is not a 7 serous carcinoma. 8 MS. O'DELL: May we go off the 9 record just for a moment, please? 10 (Recess.) 11 BY MS. O'DELL: 12 Q. Dr. Saenz, before we leave the 13 issue of endometriosis, there are -- there's a 14 recent study that's been published that reports 15 on the effect of ovarian cancer risk factors with 16 and without endometriosis. 17 Are you familiar with that? 18 A. Can you tell me who the authors 19 are? 20 Q. Sure, absolutely. 21 MS. O'DELL: We'll go ahead and 22 mark it as Exhibit 14. 23 (Exhibit No. 14 was marked for 24 identification.)</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. And you're aware of other studies, 2 are you not, Dr. Saenz, that address the 3 connection between talc and nonserous ovarian 4 cancers, which would include clear cell 5 carcinoma. True? 6 MS. CURRY: Object to the form. 7 THE WITNESS: That was not the 8 intent of this table. I'm not reporting 9 on all other nonserous histologies. I'm 10 reporting specifically on studies that 11 said they broke out the clear cell 12 histology. So this is not a report on 13 the collective grouping of the other 14 nonserous histologies. 15 BY MS. O'DELL: 16 Q. So if Schildkraut 2016 and Wu 2009 17 show an increased risk of genital talc use and -- 18 in the cases of nonserous cancers, that wasn't 19 something you intended to put in your table? 20 A. Correct, because it did not break 21 out specifically the clear cell histologies. It 22 looked at the collective grouping. 23 And I only focused here, because 24 this is Ms. Converse's case and she had clear</p>	<p style="text-align: right;">Page 137</p> <p>1 BY MS. O'DELL: 2 Q. It's the Phung study, P-H-U-N-G. 3 A. Yes, I've seen that study. 4 Q. So, Dr. Saenz, you have in front of 5 you what's been marked as Exhibit 14, a study by 6 Phung that you cited in your report. 7 Do you recall that? 8 A. Yes. 9 Q. And it's entitled "Effects of risk 10 factors for ovarian cancer in women with and 11 without endometriosis." And this is a 12 publication of the Ovarian Cancer coalition -- 13 Consortium, the OCAC. 14 A. Right. 15 Q. I'm sorry, ma'am, I couldn't hear 16 you very well. 17 A. Right. 18 Q. Thank you. And it is the work of a 19 number of authors from, you know, leading 20 institutions, cancer institutions in the United 21 States and around the world. Wouldn't you agree 22 with me? 23 MS. CURRY: Object to the form. 24 THE WITNESS: I mean, it's</p>



<p style="text-align: right;">Page 138</p> <p>1 various authors from various</p> <p>2 institutions around the world.</p> <p>3 BY MS. O'DELL:</p> <p>4 Q. Yes. And, for example, Dr. Britton</p> <p>5 Trabert is one of the authors of this study.</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. And Dr. Trabert has written</p> <p>9 extensively in the area of ovarian cancer</p> <p>10 research. True?</p> <p>11 MS. CURRY: Object to the form.</p> <p>12 THE WITNESS: Dr. Trabert has</p> <p>13 published a number of papers on ovarian</p> <p>14 cancer, that's correct.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. And if you will look further, you</p> <p>17 will see Kathryn Terry, who published the study</p> <p>18 we were referencing a few minutes ago, who pooled</p> <p>19 analysis in 2013 and has published extensively on</p> <p>20 ovarian cancer research, correct?</p> <p>21 MS. CURRY: Object to the form.</p> <p>22 THE WITNESS: Correct.</p> <p>23 BY MS. O'DELL:</p> <p>24 Q. And Dr. Terry is from Harvard</p>	<p style="text-align: right;">Page 140</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. And Dr. Berchuck is at -- the head</p> <p>3 of GYN oncology at Duke. You're aware of that?</p> <p>4 A. I know he's at Duke. I don't know</p> <p>5 what his title is.</p> <p>6 Q. And he's the past president of the</p> <p>7 Society of Gynecologic Oncology. True?</p> <p>8 A. Yes.</p> <p>9 Q. And would be a leader in the</p> <p>10 profession of GYN oncology, correct?</p> <p>11 MS. CURRY: Object to the form.</p> <p>12 THE WITNESS: I -- I think you</p> <p>13 would have to tell me what criteria</p> <p>14 you're making that evaluation.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. If you'll look at -- at the</p> <p>17 study -- if you'll turn to page 2 of the exhibit,</p> <p>18 and the purpose of this study, the objective was</p> <p>19 to evaluate the associations between the ten</p> <p>20 well- established ovarian cancer risk factors and</p> <p>21 the risk of ovarian cancer among women with and</p> <p>22 without endometriosis. Correct?</p> <p>23 A. Well, they identify ten factors</p> <p>24 that they wanted to evaluate the risk of ovarian</p>
<p style="text-align: right;">Page 139</p> <p>1 University, is she not?</p> <p>2 A. I don't actually know.</p> <p>3 Q. And then there is Dr. Cramer, who</p> <p>4 you agree has published largely in this area, and</p> <p>5 really published the first epidemiological study</p> <p>6 in ovarian cancer and genital talc use. True?</p> <p>7 A. I believe that Dr. Cramer's first</p> <p>8 article on this was back in 1982.</p> <p>9 Q. That's right. And he's published</p> <p>10 extensively since then. You would agree with</p> <p>11 that?</p> <p>12 A. Yes.</p> <p>13 Q. Would you agree with that?</p> <p>14 A. Yes.</p> <p>15 Q. And that's also true of Dr. Holly</p> <p>16 Harris, Dr. Andrew Berchuck, those are authors</p> <p>17 that have written extensively and done extensive</p> <p>18 research on ovarian cancer in a variety of</p> <p>19 contexts but also on talc use and ovarian cancer.</p> <p>20 True?</p> <p>21 MS. CURRY: Object to the form.</p> <p>22 THE WITNESS: I don't actually</p> <p>23 know all of their CVs. I am familiar</p> <p>24 with their names.</p>	<p style="text-align: right;">Page 141</p> <p>1 cancer in women with and without endometriosis,</p> <p>2 but I don't agree that those are all ten well-</p> <p>3 established risk factors.</p> <p>4 Q. I understand you don't agree, but</p> <p>5 they state they're well-established ovarian</p> <p>6 cancer risk factors, correct?</p> <p>7 A. That word is there, but I don't</p> <p>8 actually think the literature supports that.</p> <p>9 Q. I understand you don't agree, but</p> <p>10 that's what they -- that's what they write.</p> <p>11 A. They put that forth.</p> <p>12 Q. And they did -- they performed a</p> <p>13 pooled analysis of nine case-control studies in</p> <p>14 the Ovarian Cancer Association Consortium,</p> <p>15 correct?</p> <p>16 A. Yes.</p> <p>17 Q. And it involved 8,500 women with</p> <p>18 ovarian cancer, and 13,592 women who were in the</p> <p>19 control group. True?</p> <p>20 A. So -- so the nine studies included</p> <p>21 that many women, but then when they got down to</p> <p>22 actually looking at the data, and some of the</p> <p>23 different studies were completely missing data,</p> <p>24 the numbers were not that robust, and they</p>

<p style="text-align: right;">Page 142</p> <p>1 described that in their methodology section.</p> <p>2 So the results are not based on the</p> <p>3 numbers you just quoted me. Those numbers</p> <p>4 reflect the numbers that were enrolled in the</p> <p>5 studies, but as they examined each of the</p> <p>6 studies -- in fact, I think -- I think</p> <p>7 somewhere -- if I'm recollecting correctly,</p> <p>8 somewhere between three to four of the different</p> <p>9 studies actually had no data at all on some of</p> <p>10 those risk factors. So the numbers of the final</p> <p>11 calculations are much less robust.</p> <p>12 Q. And you said some of the risk</p> <p>13 factors, but they in fact -- every study had data</p> <p>14 on at least some portion of the risk factors in</p> <p>15 women with and without endometriosis. True?</p> <p>16 A. Every study had data on</p> <p>17 endometriosis, but they didn't on the various</p> <p>18 risk factors.</p> <p>19 Q. I'm not saying every study and data</p> <p>20 on every risk factor. But what I am saying is</p> <p>21 this -- that every -- it wasn't included -- let</p> <p>22 me strike that and start again.</p> <p>23 Not all of the nine case-control</p> <p>24 studies had data on every one of the ten ovarian</p>	<p style="text-align: right;">Page 144</p> <p>1 Q. I understand.</p> <p>2 A. Okay.</p> <p>3 Q. But they had some data on at least</p> <p>4 some of the risk factors.</p> <p>5 A. Correct.</p> <p>6 Q. And if you'll look on the</p> <p>7 right-hand side, Dr. Saenz, in the text of the</p> <p>8 paper, still on the same page, just above the</p> <p>9 Materials and Methods section --</p> <p>10 Are you with me, Materials and</p> <p>11 Methods?</p> <p>12 A. Okay.</p> <p>13 Q. And it says: "Our analysis</p> <p>14 considers ten well-established ovarian cancer</p> <p>15 risk factors, including body mass index (BMI);</p> <p>16 talc, i.e., talc use; family history of ovarian</p> <p>17 cancer; nonsteroidal anti-inflammatory drug</p> <p>18 (NSAID) use; breastfeeding; hormonal oral</p> <p>19 contraceptive use; parody; tubal ligation;</p> <p>20 menopausal hormone therapy use; estrogen-only and</p> <p>21 estrogen/progestin therapy; and age at menarche."</p> <p>22 Did I read that correctly?</p> <p>23 A. Yes.</p> <p>24 Q. And for talc and the data that they</p>
<p style="text-align: right;">Page 143</p> <p>1 cancer risk factors, but they did have data on</p> <p>2 some of them. True?</p> <p>3 A. Not all of the -- I'm sorry, can</p> <p>4 you -- there was a double negative in there, and</p> <p>5 it threw me.</p> <p>6 Q. I didn't intend to put a double</p> <p>7 negative. And let me just step back.</p> <p>8 On page 2 of the exhibit, page 961</p> <p>9 of the publication --</p> <p>10 Do you see in the gray box?</p> <p>11 A. Yes.</p> <p>12 Q. -- they describe the patients, and</p> <p>13 they say -- they just state there, I'm just</p> <p>14 reading it: "We included 8,500 women with</p> <p>15 ovarian cancer and 13,592 control women."</p> <p>16 That's what it states, correct?</p> <p>17 A. That's the total enrollment from</p> <p>18 the original studies, but not all of those</p> <p>19 studies contributed to the data on each of the</p> <p>20 risk factors because they never collected that</p> <p>21 data.</p> <p>22 Q. On each risk factor.</p> <p>23 A. Some of them had no data on some of</p> <p>24 the risk factors at all.</p>	<p style="text-align: right;">Page 145</p> <p>1 gleaned from their talc analysis, they found that</p> <p>2 for women who used talc and had endometriosis,</p> <p>3 the odds ratio was 1.38, with a confidence</p> <p>4 interval of 1.04 to 1.84. Correct?</p> <p>5 A. Where are we now? Oh, I got it. I</p> <p>6 found where we are.</p> <p>7 Yes, that's correct.</p> <p>8 Q. And for women who used talc --</p> <p>9 genital talc powder and did not have</p> <p>10 endometriosis, their odds ratio was 1.12 and the</p> <p>11 confidence interval was 1.01 to 1.25. Correct?</p> <p>12 A. And those are not statistically</p> <p>13 different. Those are --</p> <p>14 Q. I didn't ask you that, ma'am. I'm</p> <p>15 really -- we can get to where you want to go, but</p> <p>16 let me just get my question first.</p> <p>17 For women who used genital talc</p> <p>18 powder and did not have endometriosis, the odds</p> <p>19 ratio that they report was 1.12 with a confidence</p> <p>20 interval of 1.01 to 1.25. Correct?</p> <p>21 A. No, that's not correct.</p> <p>22 Q. It says 1.12 -- why is that not</p> <p>23 correct, ma'am? I mean, I'm not talking about</p> <p>24 the statistical interaction --</p>

<p style="text-align: right;">Page 146</p> <p>1 A. That's without endometriosis.</p> <p>2 Q. I'm talking --</p> <p>3 MS. CURRY: Don't speak</p> <p>4 over each other.</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. That's what I said, without</p> <p>7 endometriosis. It's 1.12, confidence interval</p> <p>8 1.01 to 1.25.</p> <p>9 A. So for women without endometriosis.</p> <p>10 Q. Correct.</p> <p>11 A. Okay.</p> <p>12 Q. And so both women who -- if a woman</p> <p>13 uses genital talcum powder, she's at increased</p> <p>14 risk based on this data for ovarian cancer</p> <p>15 whether she has endometriosis or does not have</p> <p>16 endometriosis. True?</p> <p>17 A. The odds ratios for talcum powder</p> <p>18 increasing the risk of ovarian cancer are</p> <p>19 positive and statistically significant as</p> <p>20 reported by these authors regardless of</p> <p>21 endometriosis status.</p> <p>22 Q. If you will turn, please, to</p> <p>23 page 964.</p> <p>24 A. My pages are listed as 1, 2, 3,</p>	<p style="text-align: right;">Page 148</p> <p>1 Q. Do you agree with that statement?</p> <p>2 A. I mean, I see the statement. Yes.</p> <p>3 Q. And then it goes on to say:</p> <p>4 "Because inflammation plays a role in the</p> <p>5 development of many cancers, including ovarian</p> <p>6 cancer, the increased risk observed specifically</p> <p>7 among women with endometriosis is plausible</p> <p>8 because overweight women with endometriosis may</p> <p>9 have higher levels of endometriosis" -- I mean,</p> <p>10 excuse me, "inflammation" -- "higher levels of</p> <p>11 inflammation."</p> <p>12 Do you see where I'm reading?</p> <p>13 A. I see where you're reading.</p> <p>14 Q. And that's what these authors</p> <p>15 state, correct?</p> <p>16 A. They stated that, but their</p> <p>17 statistical analysis does not show a difference</p> <p>18 between women with or without endometriosis.</p> <p>19 Q. It goes on to say: "Both</p> <p>20 endometriotic foci and adipose tissue produce</p> <p>21 proinflammatory cytokines, including TNF-alpha,</p> <p>22 IL-1 and IL-6. These proinflammatory cytokines</p> <p>23 have been shown to increase the risk of ovarian</p> <p>24 cancer as they promote the synthesis of</p>
<p style="text-align: right;">Page 147</p> <p>1 4, 5.</p> <p>2 Q. Okay. If that's the case, then if</p> <p>3 you will turn over to page 5.</p> <p>4 A. Okay.</p> <p>5 Q. It's the Discussion section.</p> <p>6 A. Yes, ma'am.</p> <p>7 Q. Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. The Discussion section?</p> <p>10 A. Yes.</p> <p>11 Q. And it begins by saying:</p> <p>12 "Endometriosis is a common gynecologic condition</p> <p>13 and a well- established risk factor for ovarian</p> <p>14 cancer."</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And if you go to the next</p> <p>18 paragraph, it says -- first, just in brief,</p> <p>19 "Endometriosis is considered an inflammatory</p> <p>20 disease." Four lines down.</p> <p>21 Do you see that statement,</p> <p>22 "Endometriosis is considered an inflammatory</p> <p>23 disease," reference 23?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 149</p> <p>1 prostaglandins, which in turn inhibits cell</p> <p>2 differentiation and apoptosis and enhances</p> <p>3 invasion and angiogenesis."</p> <p>4 Did I read that correctly?</p> <p>5 A. You read that correctly, but the</p> <p>6 articles that they're citing to are review</p> <p>7 articles and not actually original science with</p> <p>8 any proof of that.</p> <p>9 Q. And -- and you disagree with that</p> <p>10 statement?</p> <p>11 A. I do. There's no original science</p> <p>12 that shows that. Reference 3 is Ness, it's all</p> <p>13 hypotheses. Earlier you cited to reference 25,</p> <p>14 that's the Savant review. None of these are</p> <p>15 original science papers actually showing that.</p> <p>16 They're hypotheses.</p> <p>17 Q. And you would agree with me, ma'am,</p> <p>18 that the Savant paper, the review article, cited</p> <p>19 over 200 references supporting the statements</p> <p>20 contained in the review, correct?</p> <p>21 A. No, most of the articles that</p> <p>22 Savant cites to are other review articles, not</p> <p>23 original science. So there's not --</p> <p>24 Q. That's not really my question, but</p>

<p style="text-align: right;">Page 150</p> <p>1 --</p> <p>2 A. Ma'am --</p> <p>3 MS. CURRY: Were you finished</p> <p>4 with your answer?</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. Can you please -- I apologize, but</p> <p>7 go ahead, and I'll follow up.</p> <p>8 A. Savant's review article does not</p> <p>9 cite to the original science that demonstrates</p> <p>10 any benchtop or animal-based research that</p> <p>11 actually supports these hypotheses. It mainly</p> <p>12 cites to other review articles. And that's what</p> <p>13 the authors are doing here.</p> <p>14 Q. And you disagree with what the</p> <p>15 authors state?</p> <p>16 A. I do not believe that there is</p> <p>17 actually any science that has shown this.</p> <p>18 Q. Okay.</p> <p>19 A. In -- I'm sorry, in ovarian cancer.</p> <p>20 Q. And so you believe, I guess it's</p> <p>21 over 25 authors from respected institutions</p> <p>22 around the country and the world who published</p> <p>23 extensively in the area of ovarian cancer, just</p> <p>24 don't know what they're talking about when they</p>	<p style="text-align: right;">Page 152</p> <p>1 A. They used the word "plausible"</p> <p>2 earlier, and what they cite to is Ness, which is</p> <p>3 not --</p> <p>4 Q. Please. I'm just asking -- when</p> <p>5 they -- they're not saying that's plausible.</p> <p>6 They say "because." "Because inflammation plays</p> <p>7 a role in the development of many cancers,</p> <p>8 including ovarian cancer," that's what their --</p> <p>9 their words -- those are the words they included</p> <p>10 in their paper. True?</p> <p>11 A. That's what they said, but they</p> <p>12 also say they've been shown to increase the risk</p> <p>13 of ovarian cancer, but they don't actually show</p> <p>14 the mechanism.</p> <p>15 Q. Well, and in their data in this</p> <p>16 study, there's an increased risk of ovarian</p> <p>17 cancer for genital talc use with and without</p> <p>18 endometriosis. True?</p> <p>19 A. They report a positive odds ratio,</p> <p>20 yes.</p> <p>21 Q. And they report that not only for</p> <p>22 genital talc as a risk factor, but they report it</p> <p>23 for other risk factors as well. True?</p> <p>24 A. Actually, the authors say that</p>
<p style="text-align: right;">Page 151</p> <p>1 make these statements in their manuscript? Is</p> <p>2 that really what you're saying?</p> <p>3 MS. CURRY: Object to the form,</p> <p>4 argumentative.</p> <p>5 THE WITNESS: No, what I'm --</p> <p>6 what I'm saying is they are proposing</p> <p>7 hypotheses, and they even use words in</p> <p>8 their Discussion sections such as</p> <p>9 "plausible." They don't actually --</p> <p>10 it's a Discussion section. It's not</p> <p>11 actually science showing this. And</p> <p>12 they're putting forth some of the</p> <p>13 science that has been found, such as</p> <p>14 there can be proinflammatory cytokines,</p> <p>15 like TNF-alpha, IL-1 and IL-6. But how</p> <p>16 those actually then go on to lead to</p> <p>17 malignant transformation, they don't</p> <p>18 cite to anything that shows that.</p> <p>19 BY MS. O'DELL:</p> <p>20 Q. All right. When they say:</p> <p>21 "Because inflammation plays a role in the</p> <p>22 development of many cancers, including ovarian</p> <p>23 cancer," they don't include the word "plausible,"</p> <p>24 do they?</p>	<p style="text-align: right;">Page 153</p> <p>1 there's no statistically significant findings in</p> <p>2 their analysis. They actually say that in their</p> <p>3 Discussion section.</p> <p>4 Q. I think you're talking about the</p> <p>5 interaction.</p> <p>6 A. Correct.</p> <p>7 Q. And I wasn't talking about that. I</p> <p>8 was talking about other risk factors.</p> <p>9 A. Oh, I'm sorry. Can you direct me</p> <p>10 to where you are?</p> <p>11 Q. Let's don't get sidetracked. Let's</p> <p>12 -- so going back to where we were on this page,</p> <p>13 they go on to say: "This would also be in line</p> <p>14 with our observation of a higher risk associated</p> <p>15 with genital talc use for women with</p> <p>16 endometriosis since inflammation has been</p> <p>17 proposed as a possible biologic mechanism for</p> <p>18 talc's association with ovarian cancer."</p> <p>19 That's what the authors state,</p> <p>20 correct?</p> <p>21 A. They have, but they also say that</p> <p>22 there's no difference between the endometriosis</p> <p>23 group and the non-endometriosis group.</p> <p>24 Q. You can put that away.</p>

<p style="text-align: right;">Page 154</p> <p>1 Let's go back to Ms. Converse. On</p> <p>2 page 13 of your case-specific report, you talk</p> <p>3 about hormone replacement therapy.</p> <p>4 Let's just set the table, page 12</p> <p>5 of your -- page 13, excuse me, of your --</p> <p>6 A. I don't have a 13.</p> <p>7 MS. CURRY: Of your general</p> <p>8 report.</p> <p>9 THE WITNESS: Oh, of my general</p> <p>10 report.</p> <p>11 BY MS. O'DELL:</p> <p>12 Q. No, no, no. Forgive me -- let</p> <p>13 me give you the right page. Sorry, I think I was</p> <p>14 looking at -- I gave you the page on my outline.</p> <p>15 I don't know if that is encouraging or not, but</p> <p>16 that's what I did.</p> <p>17 Let's set the table with</p> <p>18 Ms. Converse to make sure we have the facts.</p> <p>19 Ms. Converse used hormone replacement therapy,</p> <p>20 estrogen plus progesterone, from 1997 to 2007,</p> <p>21 for ten years.</p> <p>22 A. Correct.</p> <p>23 Q. And it's your view that when</p> <p>24 Dr. Clarke-Pearson stated that combination</p>	<p style="text-align: right;">Page 156</p> <p>1 A. Yes. They're footnoted in the</p> <p>2 report right there, 21 through 24.</p> <p>3 Q. So Urban --</p> <p>4 A. Urban.</p> <p>5 Q. -- Ovarian Cancer Research Alliance</p> <p>6 risk factors --</p> <p>7 A. Yeah.</p> <p>8 Q. -- the Collaborative Group, and</p> <p>9 American Cancer Society, those are the things</p> <p>10 that you're relying on?</p> <p>11 A. Correct.</p> <p>12 Q. I would like you to turn back to</p> <p>13 what we marked as Exhibit 11, the Society of</p> <p>14 Gynecologic Oncology's ovarian cancer risk</p> <p>15 factors.</p> <p>16 Do you have that?</p> <p>17 A. Yes, ma'am.</p> <p>18 Q. And if you will go two-thirds down</p> <p>19 the page, the -- they say: Women who are on</p> <p>20 estrogen replacement therapy only, without</p> <p>21 progesterone, for more than five years, they list</p> <p>22 that as a risk factor. Women who are on estrogen</p> <p>23 replacement with progesterone are at a lower</p> <p>24 risk, meaning a lower risk of ovarian cancer.</p>
<p style="text-align: right;">Page 155</p> <p>1 hormone therapy, progesterone plus estrogen, does</p> <p>2 not increase the risk of ovarian cancer, that he</p> <p>3 was incorrect?</p> <p>4 A. That's correct.</p> <p>5 Q. And you go on to state that:</p> <p>6 "Ms. Converse's use of HRT, combination estrogen</p> <p>7 plus progesterone therapy, for greater than ten</p> <p>8 years, the risk of developing ovarian cancer was</p> <p>9 increased by 20 to 40 percent."</p> <p>10 You state that on page 6 of your</p> <p>11 Converse case-specific report.</p> <p>12 A. Yep.</p> <p>13 Q. And is it your opinion that her</p> <p>14 increased -- her use of combination HRT increased</p> <p>15 her risk by 20 to 40 percent?</p> <p>16 A. Yes.</p> <p>17 Q. And what's the basis for that</p> <p>18 statement?</p> <p>19 A. The various studies that have shown</p> <p>20 an increased risk of developing ovarian cancer</p> <p>21 with increasing years of use of HRT.</p> <p>22 Q. So do you have a specific citation</p> <p>23 other than just various -- do you have a specific</p> <p>24 citation?</p>	<p style="text-align: right;">Page 157</p> <p>1 That's what they state, correct?</p> <p>2 A. No.</p> <p>3 MS. CURRY: Object to the form.</p> <p>4 THE WITNESS: That's -- they're</p> <p>5 saying women that are on combination</p> <p>6 therapy are at a lower risk than women</p> <p>7 that are on the risk of estrogen alone,</p> <p>8 but they're not at a lower risk of</p> <p>9 developing ovarian cancer.</p> <p>10 BY MS. O'DELL:</p> <p>11 Q. That's your -- that's your</p> <p>12 understanding?</p> <p>13 A. Well, yes, because -- in fact, on</p> <p>14 page 2 of the same document is where they list</p> <p>15 things that reduce your risks, and they don't say</p> <p>16 estrogen alone therapy reduces your risk there.</p> <p>17 These are risk factors that --</p> <p>18 Q. I'm on Exhibit 11 for SGO.</p> <p>19 A. So am I.</p> <p>20 Q. Okay.</p> <p>21 A. If you flip over, some things</p> <p>22 reduce a woman's risk of developing ovarian</p> <p>23 cancer. Taking birth control pills reduces a</p> <p>24 woman's risk, et cetera, et cetera. They do not</p>



<p style="text-align: right;">Page 158</p> <p>1 say that taking estrogen alone reduces your risk.</p> <p>2 Estrogen alone --</p> <p>3 Q. Well, ma'am, why would they say it</p> <p>4 there if they've already said women who are on</p> <p>5 estrogen replacement therapy with progesterone</p> <p>6 are at a lower risk? They've already said it in</p> <p>7 this very short document.</p> <p>8 A. That's not --</p> <p>9 MS. CURRY: Object to the form.</p> <p>10 THE WITNESS: That's not risk</p> <p>11 reducing overall. They're at a lower</p> <p>12 risk than women that are on</p> <p>13 estrogen-only therapy, but they're not</p> <p>14 at a reduced risk over the background</p> <p>15 population risk.</p> <p>16 BY MS. O'DELL:</p> <p>17 Q. Let me ask you to look at ACOG's</p> <p>18 list of risk factors for ovarian cancer. Exhibit</p> <p>19 10.</p> <p>20 A. I have it.</p> <p>21 Q. And they don't include hormone</p> <p>22 replacement therapy as a risk factor for ovarian</p> <p>23 cancer. True?</p> <p>24 A. They don't list it at all, that's</p>	<p style="text-align: right;">Page 160</p> <p>1 risk factors.</p> <p>2 (Exhibit No. 15 was marked for</p> <p>3 identification.)</p> <p>4 BY MS. O'DELL:</p> <p>5 Q. Do you have it in front of you,</p> <p>6 ma'am?</p> <p>7 A. Yes. Thank you.</p> <p>8 Q. Thank you. So, Dr. Saenz, what has</p> <p>9 been marked as Exhibit 15 is a document published</p> <p>10 by the CDC, "Ovarian Cancer Risk Factors,"</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. And the CDC does not list hormone</p> <p>14 replacement therapy use as a risk factor -- let</p> <p>15 me strike that.</p> <p>16 If you'll go down to the bottom of</p> <p>17 the page, it says: "Some studies suggest that</p> <p>18 women who take estrogen by itself without</p> <p>19 progesterone for ten or more years may have an</p> <p>20 increased risk of ovarian cancer."</p> <p>21 They do not include there estrogen</p> <p>22 plus progesterone, correct?</p> <p>23 A. They do not, but other places do.</p> <p>24 And they also do list an Ashkenazi Jewish</p>
<p style="text-align: right;">Page 159</p> <p>1 correct.</p> <p>2 Q. And there are published studies</p> <p>3 that establish that estrogen plus progesterone</p> <p>4 hormone therapy does in fact reduce the risk of</p> <p>5 ovarian cancer, correct?</p> <p>6 MS. CURRY: Object to the form.</p> <p>7 THE WITNESS: That is not the</p> <p>8 current thinking in the management of</p> <p>9 patients with ovarian cancer. Hormone</p> <p>10 replacement therapy is thought, whether</p> <p>11 in combination with estrogen and</p> <p>12 progesterone or estrogen alone, to</p> <p>13 increase your risk.</p> <p>14 MS. O'DELL: Let me mark as</p> <p>15 exhibit -- are we on 16 or 15?</p> <p>16 MS. CURRY: 15.</p> <p>17 MS. O'DELL: Okay. Thank you.</p> <p>18 Exhibit 15, the CDC ovarian</p> <p>19 cancer risk factors.</p> <p>20 MS. O'DELL: Do you have</p> <p>21 those -- do you have that, Paula?</p> <p>22 MS. BROWN: Sorry, what was</p> <p>23 that?</p> <p>24 MS. O'DELL: CDC ovarian cancer</p>	<p style="text-align: right;">Page 161</p> <p>1 background.</p> <p>2 Q. If you will look -- I want to turn</p> <p>3 your attention to what I'm going to mark as</p> <p>4 Exhibit 16, Dr. Saenz.</p> <p>5 MS. O'DELL: It's a paper by --</p> <p>6 the first author is Alice Lee. And it</p> <p>7 should be marked as Lee, L-E-E, and</p> <p>8 it's -- if you have it there, Paula, I</p> <p>9 just want to make sure. If not, I can</p> <p>10 put it up.</p> <p>11 MS. BROWN: I have it.</p> <p>12 MS. O'DELL: Okay.</p> <p>13 (Exhibit No. 16 was marked for</p> <p>14 identification.)</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. All right, ma'am, do you have it?</p> <p>17 A. I do.</p> <p>18 Q. Okay. And this is a 2020 study</p> <p>19 entitled "Estrogen Plus Progestin Therapy --</p> <p>20 Hormone Therapy and Ovarian Cancer: A</p> <p>21 Complicated Relationship Explored" published in</p> <p>22 May of 2020 in the Journal of Epidemiology. Is</p> <p>23 that correct?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 162</p> <p>1 Q. And this is also a publication of</p> <p>2 the Ovarian Cancer Association Consortium. True?</p> <p>3 A. Correct.</p> <p>4 Q. And it evaluates -- if you'll turn</p> <p>5 over to what is my page 3 of the publication, it</p> <p>6 evaluates primary data from five population based</p> <p>7 case-control studies in the Ovarian Cancer</p> <p>8 Association Consortium, including 1,509</p> <p>9 postmenopausal ovarian cancer cases and 2,295</p> <p>10 postmenopausal controls. Correct?</p> <p>11 A. Correct.</p> <p>12 Q. And they looked at ever</p> <p>13 postmenopausal use of continuous</p> <p>14 estrogen-progestin combined therapy was not</p> <p>15 associated with the increased risk of ovarian</p> <p>16 cancer overall.</p> <p>17 Do you see that?</p> <p>18 A. I do.</p> <p>19 Q. And they conclude that: "Given</p> <p>20 that estrogen alone therapy has been shown to be</p> <p>21 associated with increased risk of ovarian cancer,</p> <p>22 these findings are consistent with the hypothesis</p> <p>23 that adding progesterone each day ameliorates the</p> <p>24 carcinogenic effects of estrogen on cells of</p>	<p style="text-align: right;">Page 164</p> <p>1 Q. And if so, which ones?</p> <p>2 A. So she -- she breastfed one of her</p> <p>3 children for 13 months, so that should have led</p> <p>4 to a decreased risk of developing ovarian cancer.</p> <p>5 She had used oral contraceptives</p> <p>6 for more than ten years, so that should have</p> <p>7 decreased her risk of developing ovarian cancer.</p> <p>8 And she had her first child at age 25.</p> <p>9 Q. And she had two children, correct?</p> <p>10 A. I believe so.</p> <p>11 Q. And that would -- having two</p> <p>12 children would also decrease her risk of ovarian</p> <p>13 cancer. True?</p> <p>14 A. That's correct.</p> <p>15 Q. And what weight did you give for</p> <p>16 protective factors in reaching your opinions?</p> <p>17 MS. CURRY: Object to the form.</p> <p>18 THE WITNESS: So you can't take</p> <p>19 data on risks of either increased or</p> <p>20 decreased and do an attributable risk</p> <p>21 analysis for any one individual person.</p> <p>22 At the end of the day, she got</p> <p>23 ovarian cancer, and I think hers is a</p> <p>24 case that illustrates that even if you</p>
<p style="text-align: right;">Page 163</p> <p>1 origin for all histotypes of ovarian cancer."</p> <p>2 Did I read that correctly?</p> <p>3 A. That was their conclusion. But</p> <p>4 you -- I mean, you do -- the numbers you were</p> <p>5 just showing me -- obviously, I have not read</p> <p>6 this whole paper. The finding was actually it</p> <p>7 didn't achieve statistical significance in the</p> <p>8 combination therapy because the confidence</p> <p>9 interval overlapped 1. And there are other</p> <p>10 papers that show that the risk is increased with</p> <p>11 both combination and estrogen alone HRT.</p> <p>12 Q. Clearly, this study and these</p> <p>13 authors, the data states that estrogen plus</p> <p>14 progestin combined therapy was not associated</p> <p>15 with increased risk of ovarian cancer overall.</p> <p>16 That was their conclusion.</p> <p>17 A. That's not a statistically</p> <p>18 significant finding, though.</p> <p>19 Q. Let me turn back to your Converse</p> <p>20 report and ask, did you consider any factors that</p> <p>21 increased -- excuse me. Strike that.</p> <p>22 Did you consider any factors that</p> <p>23 decreased Ms. Converse's risk of ovarian cancer?</p> <p>24 A. I believe --</p>	<p style="text-align: right;">Page 165</p> <p>1 have protective -- quote/unquote,</p> <p>2 protective factors, things that I term</p> <p>3 as factors that reduce your risk, you</p> <p>4 can still get ovarian cancer.</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. What is your methodology for -- or</p> <p>7 let me strike that and reask it.</p> <p>8 Do you balance -- do you consider</p> <p>9 risk factors in conjunction with protective</p> <p>10 factors to evaluate an individual's overall risk</p> <p>11 of developing ovarian cancer?</p> <p>12 MS. CURRY: Object to the form.</p> <p>13 THE WITNESS: In a patient</p> <p>14 that's already developed the disease or</p> <p>15 in just a random woman?</p> <p>16 BY MS. O'DELL:</p> <p>17 Q. Let's start out with in general.</p> <p>18 A. In general, I mean, we know that</p> <p>19 there are risk factors that reduce your risk of</p> <p>20 developing cancer, and so in terms of women, I</p> <p>21 guess, you know, counseling them whether or not</p> <p>22 they should use birth control pills to reduce</p> <p>23 their risk of developing ovarian cancer, I</p> <p>24 certainly advise women to do that that are</p>

<p style="text-align: right;">Page 166</p> <p>1 premenopausal, and I advise women that are high 2 risk to do that. 3 But you -- I think I would advise 4 anybody, and if they were saying, What can I do 5 to reduce my risk? I would advise them of the 6 things that we know can reduce their risk. But I 7 can't quantify those things for an individual 8 patient. 9 Q. Okay. 10 MS. O'DELL: We've been going 11 probably about 45 more minutes since 12 last break. I would like to go off the 13 record. 14 THE REPORTER: We're off the 15 record. 16 (Lunch recess.) 17 BY MS. O'DELL: 18 Q. Dr. Saenz, let me ask you to turn 19 back to your general report, Exhibit 2. And I 20 want to ask you some questions about your general 21 opinions. 22 And as I launch into that, I want 23 to ask you specifically about the book paper that 24 you cite. If you'll turn to page 15 of your</p>	<p style="text-align: right;">Page 168</p> <p>1 the risk of ovarian cancer development. 2 Q. They don't say in there -- 3 MS. O'DELL: And I will mark it 4 for the record, and I believe we're on 5 Exhibit -- is it 16 or 17? 6 MS. CURRY: It's 17. 7 MS. O'DELL: Okay. Thank you. 8 -- the Burke paper. 9 (Exhibit No. 17 was marked for 10 identification.) 11 MS. O'DELL: And they -- I would 12 also mark at the same time the 13 appendix -- appendices as Exhibit 18 of 14 the Burke paper. 15 (Exhibit No. 18 was marked for 16 identification.) 17 THE WITNESS: I have it. 18 BY MS. O'DELL: 19 Q. Okay. Great. 20 And Exhibit 17 is the Burke paper 21 you mention, right, at footnote 71, just for the 22 record. 23 A. Yes. 24 Q. And I'll ask you to turn to</p>
<p style="text-align: right;">Page 167</p> <p>1 general report, you cite, footnote 71, Burke, 2 "Executive Summary of Ovarian Cancer Evidence 3 Review Conference" with appendices. 4 Do you see that? 5 A. Yes, ma'am. 6 Q. And I want to understand the 7 emphasis you're placing on Burke. 8 First, you say in your report: "As 9 recently as May 2023, at ACOG's annual clinical 10 and scientific meeting, the executive summary of 11 the ovarian cancer evidence review conference was 12 presented, and the authors concluded that," 13 quote, "the studies regarding the use of talcum 14 powder and the risk of ovarian cancer are 15 heterogeneous." 16 Did I read that correctly? 17 A. Yes. 18 Q. And what is your understanding of 19 what they're saying about heterogeneity in that 20 state? 21 A. That because of the heterogeneity 22 of the scientific articles that have been 23 published to date, there is no clear evidence 24 that the perineal application of talc increases</p>	<p style="text-align: right;">Page 169</p> <p>1 page 183. 2 A. Okay. 3 Q. The left-hand column, and in the 4 upper -- the first paragraph -- do you see that? 5 A. Yes. 6 Q. And this is in a section entitled 7 "Lifestyle," and the last sentence states: "Our 8 review found heterogeneity in the studies on the 9 use of talcum powder and ovarian cancer risk, 10 Appendices 3," and it gives a link, "provides a 11 complete evidence summary." 12 That is the complete statement in 13 this document regarding talcum powder, correct? 14 A. Well, along with -- 15 MS. CURRY: Object -- sorry. 16 THE WITNESS: Along with the 17 appendix they refer you to. 18 BY MS. O'DELL: 19 Q. I understand, but there's no other 20 reference, discussion, explanation regarding talc 21 in this document besides that one sentence. 22 True? 23 A. In 17, no, but 18 is part of 17, 24 because --</p>

<p style="text-align: right;">Page 170</p> <p>1 Q. Yes.</p> <p>2 A. Yeah.</p> <p>3 Q. I understand.</p> <p>4 So let's turn to 18. And I'll ask</p> <p>5 you if you'll turn to page 27 of 71 in</p> <p>6 Exhibit 18.</p> <p>7 A. I'm there.</p> <p>8 Q. Are you there?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Thank you.</p> <p>11 And this is the entirety of the</p> <p>12 discussion on talcum powder, correct?</p> <p>13 A. Correct.</p> <p>14 Q. And they list certain studies</p> <p>15 under -- in this section. And if you'll notice,</p> <p>16 the first reference is 18, and it -- in the third</p> <p>17 paragraph, it cites to 21. So, really, it's 18</p> <p>18 through 21 of the references are those that refer</p> <p>19 to genital talc and ovarian cancer.</p> <p>20 Do you see what I'm saying here?</p> <p>21 MS. CURRY: Object to the form.</p> <p>22 THE WITNESS: Actually, it's 17</p> <p>23 through 21, because in the next</p> <p>24 paragraph they reference the NCCN</p>	<p style="text-align: right;">Page 172</p> <p>1 Q. Right. But they don't include some</p> <p>2 of the meta-analyses. True?</p> <p>3 A. Some of these -- oh, you mean some</p> <p>4 of the other meta-analyses that have been</p> <p>5 published?</p> <p>6 Q. Correct.</p> <p>7 A. No, they don't.</p> <p>8 Q. That's right. And they don't</p> <p>9 include the other pooled studies that have been</p> <p>10 published, correct?</p> <p>11 A. That's correct.</p> <p>12 Q. And -- and so they cite these four,</p> <p>13 but there's obviously a whole body of literature</p> <p>14 that is not referenced in this short summary.</p> <p>15 True?</p> <p>16 MS. CURRY: Object to the form.</p> <p>17 THE WITNESS: That's correct.</p> <p>18 BY MS. O'DELL:</p> <p>19 Q. And they go through the studies,</p> <p>20 and at the fourth paragraph, last paragraph, they</p> <p>21 conclude: "The studies regarding the use of</p> <p>22 talcum powder and the risk of ovarian cancer are</p> <p>23 heterogeneous."</p> <p>24 That's the same statements included</p>
<p style="text-align: right;">Page 171</p> <p>1 guidelines, and that's 17.</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. Okay. In terms of the scientific</p> <p>4 studies, if you'll turn to the references on</p> <p>5 page 40 of 71, you'll see -- and tell me when</p> <p>6 you're there.</p> <p>7 A. I'm there.</p> <p>8 Q. So 40 of 71 lists reference 17</p> <p>9 through 21, and 17 is the NCCN guidelines that</p> <p>10 you referred to, and 18 through 21 are the talc</p> <p>11 ovarian cancer studies that they reference in</p> <p>12 this appendices, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Huncharek, Berge, Taher, and</p> <p>15 Penninkilampi.</p> <p>16 A. Yes.</p> <p>17 Q. And those are only four</p> <p>18 of essentially more than 40 studies that are</p> <p>19 referenced in this summary. True?</p> <p>20 A. Those are the four they reference,</p> <p>21 but some of those studies that they referenced</p> <p>22 are meta-analyses, and so they do include data</p> <p>23 from those other studies that you are saying are</p> <p>24 the 40 studies.</p>	<p style="text-align: right;">Page 173</p> <p>1 in the publication, correct?</p> <p>2 A. Yes.</p> <p>3 Q. There's no statement from ACOG</p> <p>4 regarding cause, whether talc is causal or</p> <p>5 noncausal, correct? They never use the word</p> <p>6 "cause."</p> <p>7 A. They do not use the word "cause,"</p> <p>8 but they say that talc has not been conclusively</p> <p>9 associated with the development of ovarian</p> <p>10 cancer.</p> <p>11 Q. Well, actually what they say,</p> <p>12 ma'am, is on the basis of seven studies, the NCCN</p> <p>13 guidelines state that environmental factors have</p> <p>14 not been conclusively associated with the</p> <p>15 development of ovarian cancer. They are quoting</p> <p>16 and referencing the NCCN guidelines there,</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. It's not a statement of what ACOG</p> <p>20 is concluding.</p> <p>21 MS. CURRY: Object to the form.</p> <p>22 THE WITNESS: I disagree with</p> <p>23 that. They're putting that statement in</p> <p>24 there, and this is an ACOG document. So</p>

<p style="text-align: right;">Page 174</p> <p>1 I disagree with that. I think that they</p> <p>2 are allowed to quote from another</p> <p>3 document and then put it in their</p> <p>4 document. They're agreeing with that</p> <p>5 statement.</p> <p>6 BY MS. O'DELL:</p> <p>7 Q. I'm not saying they're not allowed</p> <p>8 to quote. That's not my point.</p> <p>9 And the NCCN guidelines talk about</p> <p>10 environmental factors, correct?</p> <p>11 A. And whether or not they increase</p> <p>12 the risk of developing ovarian cancer, correct.</p> <p>13 Q. That's not what they say actually,</p> <p>14 is it, Dr. Saenz?</p> <p>15 Because what they state is not</p> <p>16 increased risk. What they state is that:</p> <p>17 "Environmental factors have not been conclusively</p> <p>18 associated with the development of ovarian</p> <p>19 cancer." That's the statement that's quoted,</p> <p>20 correct?</p> <p>21 A. That's the statement, but that's</p> <p>22 whether or not they increase risk. The</p> <p>23 development of ovarian cancer is whether or not</p> <p>24 it increases the risk of development.</p>	<p style="text-align: right;">Page 176</p> <p>1 significant increased risk of ovarian cancer with</p> <p>2 genital talc. True?</p> <p>3 A. That's what they reported. But</p> <p>4 they --</p> <p>5 Q. And if you -- just -- just if you</p> <p>6 could bear with me -- Berge, in the second</p> <p>7 paragraph, reports a 22 percent increased risk as</p> <p>8 statistically significant.</p> <p>9 MS. CURRY: Object to the form.</p> <p>10 BY MS. O'DELL:</p> <p>11 Q. Do you see that?</p> <p>12 A. That's what the study reported</p> <p>13 based --</p> <p>14 Q. And so --</p> <p>15 Sorry.</p> <p>16 A. No, go ahead.</p> <p>17 Q. And so this document includes data</p> <p>18 that shows an increased risk of ovarian cancer</p> <p>19 with genital talc use, correct?</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 THE WITNESS: And it also</p> <p>22 includes data that shows that there's</p> <p>23 not an increased risk. That's what they</p> <p>24 mean by the data are heterogeneous, the</p>
<p style="text-align: right;">Page 175</p> <p>1 Q. In your mind, and based on --</p> <p>2 increased risk is the same thing as something</p> <p>3 being conclusively associated with the</p> <p>4 development of a disease. Is that your</p> <p>5 testimony?</p> <p>6 A. The statement here says that:</p> <p>7 "Environmental factors have not been conclusively</p> <p>8 associated with the development of ovarian</p> <p>9 cancer."</p> <p>10 So there is no data that</p> <p>11 environmental factors alter the risk of the</p> <p>12 development of ovarian cancer.</p> <p>13 Q. It doesn't say there's no data in</p> <p>14 the statement, does there, ma'am?</p> <p>15 A. That's what it does in terms of the</p> <p>16 analysis. It says that there is -- these factors</p> <p>17 have not been conclusively associated with the</p> <p>18 development.</p> <p>19 Q. And that is not the equivalent of</p> <p>20 no data.</p> <p>21 A. No, it's the summary of the data.</p> <p>22 Q. I know, ma'am. I know.</p> <p>23 Huncharek, the study cited by this</p> <p>24 summary, reports a 33 percent statistically</p>	<p style="text-align: right;">Page 177</p> <p>1 studies are heterogeneous.</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. Is there any study that they've</p> <p>4 cited and they've included the data that doesn't</p> <p>5 show a statistically significant increased risk?</p> <p>6 A. So when they are pointing out in</p> <p>7 the Berge analysis, they say -- and for the</p> <p>8 cohort studies, the HR is 1.02 with the</p> <p>9 confidence intervals of 0.85 to 1.2. That's --</p> <p>10 Q. All right.</p> <p>11 A. That's a finding that does not show</p> <p>12 an increased risk. That's what they mean by the</p> <p>13 studies are heterogeneous.</p> <p>14 Q. And you think that it is the</p> <p>15 comparison of the cohort and the -- the cohort</p> <p>16 data to the other studies is what they're</p> <p>17 referring to when they say heterogeneous?</p> <p>18 MS. CURRY: Object to the form.</p> <p>19 THE WITNESS: That's part of it.</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. What else are they referring to?</p> <p>22 A. The studies that they analyzed, and</p> <p>23 here we're referring to the statement from the</p> <p>24 NCCN that looked at seven studies, and they say</p>



<p style="text-align: right;">Page 178</p> <p>1 the studies regarding the use of talcum powder  2 and the risk of ovarian cancer are heterogeneous.  3 That means that they are --  4 Q. Let me just ask --  5 A. That means that they're not  6 consistent.  7 Q. In the NCCN guidelines --  8 MS. O'DELL: And I'm going to  9 mark those as Exhibit 19.  10 (Exhibit No. 19 was marked for  11 identification.)  12 BY MS. O'DELL:  13 Q. And if you will turn, Dr. Saenz, to  14 MS-3.  15 A. Yes, I'm there.  16 Q. And the extent of the NCCN  17 guidelines version February 2024 for ovarian  18 cancer, they extended their comment that would be  19 relevant to talc is: "Environmental factors have  20 been investigated, such as talc, but so far they  21 have not been conclusively associated with the  22 development of this neoplasm."  23 Did I read that correctly?  24 A. Yes.</p>	<p style="text-align: right;">Page 180</p> <p>1 Q. And for Berge, for all studies,  2 it's a statistically significant increased risk,  3 correct?  4 A. But the Berge study actually showed  5 that the weight of that statistically significant  6 finding was from the case-control studies  7 because, as we just pointed out, when they pulled  8 out the cohort studies, that finding was not  9 significant.  10 Q. Oh, they say that they, and  11 assuming environmental factors means talc in this  12 context, have not been conclusively associated  13 with the development of neoplasm -- of this  14 neoplasm.  15 And you agree with that statement?  16 A. Yes.  17 Q. And what would it take, Dr. Saenz,  18 for an association with genital use of talc to,  19 quote, conclusively be associated with ovarian  20 cancer?  21 A. It would require that the  22 literature be consistent to not have positive and  23 negative findings within the various studies. It  24 would take a consistent strength of association.</p>
<p style="text-align: right;">Page 179</p> <p>1 Q. And they cite 56 through 63, I  2 believe it is.  3 MS. CURRY: 66. 56 through 66  4 is what they cite.  5 MS. O'DELL: Thank you.  6 BY MS. O'DELL:  7 Q. And if you look at 56 is -- is  8 Taher. Do you see that?  9 A. Yes.  10 Q. And you are aware that Taher showed  11 an increase risk of ovarian cancer with talc use,  12 correct?  13 A. I believe that they did, yes.  14 Q. And you're aware also that in 58  15 that Penninkilampi reported a statistically  16 significant increased risk with the use of  17 genital talc, correct?  18 MS. CURRY: Object to the form.  19 THE WITNESS: For the  20 case-control studies but not the cohort.  21 BY MS. O'DELL:  22 Q. The overall data point is  23 statistically significant, correct?  24 A. Correct.</p>	<p style="text-align: right;">Page 181</p> <p>1 It would take evidence of a biologic gradient.  2 And it would take evidence of biologic  3 plausibility for the mechanism of migration as  4 well as the mechanism of mutagenesis.  5 Q. Do you view conclusively as being a  6 hundred percent certain?  7 MS. CURRY: Object to the form.  8 THE WITNESS: No.  9 BY MS. O'DELL:  10 Q. How much less than a hundred  11 percent do you have to be for it to be  12 conclusive?  13 MS. CURRY: Object to the form.  14 THE WITNESS: I can't quantify  15 that for you because it is a subjective  16 evaluation of the totality of the data.  17 BY MS. O'DELL:  18 Q. Is it necessary for cause to be  19 established that it be done -- that it be  20 accomplished conclusively?  21 MS. CURRY: Object to the form.  22 THE WITNESS: I think that for  23 cause to be established, there has to  24 be, as I said, consistency in the data,</p>

<p style="text-align: right;">Page 182</p> <p>1 and more than just a hypothesis. There</p> <p>2 has to be some level of either in vivo</p> <p>3 or in vitro studies that can explain the</p> <p>4 mechanism of malignant transformation as</p> <p>5 is put forth and hypothesized about, as</p> <p>6 well as consistency in the epidemiologic</p> <p>7 data and in the migration data in terms</p> <p>8 of the actual ability of talc to move</p> <p>9 from a perineal application to something</p> <p>10 that is now inciting an inflammatory</p> <p>11 response in the ovaries. I don't think</p> <p>12 we have any data for that.</p> <p>13 BY MS. O'DELL:</p> <p>14 Q. You and I have talked about that at</p> <p>15 length. We'll leave that for another day just to</p> <p>16 conserve time.</p> <p>17 Would it be fair to say that</p> <p>18 neither Burke nor the NCCN guidelines cite to the</p> <p>19 in vitro data regarding talc?</p> <p>20 A. They do not cite to that, that is</p> <p>21 correct.</p> <p>22 Q. And neither Burke nor the NCCN</p> <p>23 guidelines cite to the International Agency for</p> <p>24 Research on Cancer 2012 monograph regarding</p>	<p style="text-align: right;">Page 184</p> <p>1 MS. CURRY: What is Exhibit 20?</p> <p>2 MS. O'DELL: I was just about</p> <p>3 to announce it. Sorry. I had a little</p> <p>4 pause there.</p> <p>5 It's entitled "Epithelial</p> <p>6 Ovarian Cancer." It's by Arora.</p> <p>7 (Exhibit No. 20 was marked for</p> <p>8 identification.)</p> <p>9 BY MS. O'DELL:</p> <p>10 Q. Let me know when you have it,</p> <p>11 please.</p> <p>12 A. Okay, I have it.</p> <p>13 Q. And I'll represent to you,</p> <p>14 Dr. Saenz, that this is a book chapter that was</p> <p>15 obtained from the NCBI Bookshelf from the series</p> <p>16 of National Library of Medicine, National</p> <p>17 Institutes of Health, published in -- it was last</p> <p>18 updated May 6, 2024.</p> <p>19 Do you see that?</p> <p>20 A. Oh, yes. Okay.</p> <p>21 Q. And this is an article that was</p> <p>22 published by -- or written by four authors,</p> <p>23 including Elsa Vadakekut.</p> <p>24 Do you see that?</p>
<p style="text-align: right;">Page 183</p> <p>1 asbestos, correct?</p> <p>2 A. In this section -- well, in this</p> <p>3 section that we're looking at, they do not cite</p> <p>4 to that, that is correct. I'm not looking at the</p> <p>5 entire document, so I don't know if that's</p> <p>6 anywhere else.</p> <p>7 Q. I'm talking about only their</p> <p>8 ovarian cancer talcum powder discussion.</p> <p>9 A. Correct, in this section of the</p> <p>10 paper, they do not cite to that.</p> <p>11 Q. And they do not cite to the O'Brien</p> <p>12 2020 publication, correct?</p> <p>13 A. That's correct.</p> <p>14 Q. They do not cite to the O'Brien</p> <p>15 2024 publication, correct?</p> <p>16 A. Well, Burke was published before</p> <p>17 that anyway, so they're not going to cite to</p> <p>18 that. And I think the NCCN guidelines came out</p> <p>19 before O'Brien was published as well.</p> <p>20 Q. And they do not cite to the Woolen</p> <p>21 2022 meta-analysis. True?</p> <p>22 A. That's correct.</p> <p>23 Q. I would like to ask you to turn</p> <p>24 your attention to Exhibit No. 20.</p>	<p style="text-align: right;">Page 185</p> <p>1 A. Yes.</p> <p>2 Q. And she's from the American College</p> <p>3 of Osteopathic Obstetricians and Gynecologists.</p> <p>4 Do you see that?</p> <p>5 A. No. Where am I supposed to see</p> <p>6 that?</p> <p>7 Q. Number 3.</p> <p>8 A. I see her name, but I don't know</p> <p>9 what her training is.</p> <p>10 Q. It's actually just right below, her</p> <p>11 affiliation --</p> <p>12 A. It's not there. Yeah, it's not</p> <p>13 there.</p> <p>14 Q. Okay.</p> <p>15 A. And it's really blurry -- okay.</p> <p>16 No.</p> <p>17 Q. I'm sorry if it's blurry. I'll</p> <p>18 just try to -- it's not a big point.</p> <p>19 A. Okay.</p> <p>20 Q. Let me ask you to turn to page 2.</p> <p>21 And I want to make sure you have what I'm looking</p> <p>22 at, and that is there's a section entitled</p> <p>23 "Etiology. Ovarian Cancer Risk Factors."</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 186</p> <p>1 Q. And it lists "perineal talc use,"</p> <p>2 correct?</p> <p>3 A. Yes, it does.</p> <p>4 Q. Thank you, ma'am. I want to put</p> <p>5 that aside.</p> <p>6 I want to turn to your report --</p> <p>7 A. I'm sorry, which -- so -- may I</p> <p>8 ask? So was the point of this just for me to</p> <p>9 read into the record that this one paper cites</p> <p>10 perineal talc use without any data or evidence or</p> <p>11 opportunity to analyze this?</p> <p>12 Q. I guess, Dr. Saenz, the point is</p> <p>13 I've got seven hours to get through this, and I'm</p> <p>14 just doing it as quickly and as efficiently as I</p> <p>15 can, and so --</p> <p>16 A. Right, but I -- I appreciate that,</p> <p>17 but I don't understand the relevance of this</p> <p>18 exhibit.</p> <p>19 Q. I understand. I understand.</p> <p>20 Sometimes our difference in point of views will</p> <p>21 make it difficult for us to agree on the</p> <p>22 relevance of something. I understand.</p> <p>23 Let me ask you to go back to your</p> <p>24 report on page 13, please. And actually page 16.</p>	<p style="text-align: right;">Page 188</p> <p>1 it for talc?</p> <p>2 Q. Yes.</p> <p>3 A. No, I have not.</p> <p>4 Q. Turn over to page 13. Please</p> <p>5 excuse me, 18. I'm sorry, I keep saying 13.</p> <p>6 A. You know that's Taylor Swift's</p> <p>7 lucky number.</p> <p>8 Q. I heard that. I'm always looking</p> <p>9 for a lucky number.</p> <p>10 You say in the middle of the top</p> <p>11 paragraph, and beginning with "Additionally":</p> <p>12 "Additionally, the literature on the use of</p> <p>13 anti-inflammatory agents aspirin and NSAIDs has</p> <p>14 not consistently been shown to decrease the risk</p> <p>15 of developing ovarian cancer as it has in</p> <p>16 malignancies that are known to arise from</p> <p>17 induction of chronic inflammatory state, e.g.,</p> <p>18 colon cancer."</p> <p>19 Did I read that correctly?</p> <p>20 A. Yes, ma'am.</p> <p>21 Q. And you would agree with me that</p> <p>22 there have been studies that have shown that the</p> <p>23 consistent use of aspirin decreases the risk of</p> <p>24 ovarian cancer. True?</p>
<p style="text-align: right;">Page 187</p> <p>1 A. Okay, I'm there.</p> <p>2 Q. Thank you.</p> <p>3 In your Talc and the Risk of</p> <p>4 Ovarian Cancer - Overview section, you added in</p> <p>5 your new report a reference to eating processed</p> <p>6 meat and chronic physical inactivity or watching</p> <p>7 TV for greater than five hours a day, and you</p> <p>8 added references footnotes 73 through 75.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And the question I have is,</p> <p>12 Dr. Saenz, would you agree with me that in regard</p> <p>13 to eating processed meat, that there are not more</p> <p>14 than 40 studies that examined that issue</p> <p>15 regarding ovarian cancer?</p> <p>16 MS. CURRY: Object to the form.</p> <p>17 THE WITNESS: I -- I don't know</p> <p>18 how many studies there are on eating</p> <p>19 processed meat.</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. Have you done a systematic review</p> <p>22 for either processed meats or physical</p> <p>23 inactivities and ovarian cancer?</p> <p>24 A. To the same degree that I've done</p>	<p style="text-align: right;">Page 189</p> <p>1 MS. CURRY: Object to the form.</p> <p>2 THE WITNESS: So there have been</p> <p>3 some studies that show that low dose</p> <p>4 aspirin is associated with a decreased</p> <p>5 risk of ovarian cancer, but that regular</p> <p>6 dose aspirin or aspirin use actually</p> <p>7 for -- I think it was longer than --</p> <p>8 more than six times a week and more than</p> <p>9 six years has perhaps either no effect</p> <p>10 or maybe even increases the risk. So</p> <p>11 the literature that has been published</p> <p>12 on aspirin and the use of NSAIDs and the</p> <p>13 risk of developing ovarian cancer has</p> <p>14 been inconsistent.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. You were referring to -- or</p> <p>17 remembering a specific study regarding aspirin</p> <p>18 use, and I'd ask you which one you were thinking</p> <p>19 of.</p> <p>20 A. I think there was a study by Barnes</p> <p>21 at one point on aspirin use.</p> <p>22 I think there was also -- let me</p> <p>23 find -- there was another study -- 233, 234. So,</p> <p>24 oh, sorry, there was the Wu study. There was</p>

<p style="text-align: right;">Page 190</p> <p>1 also the Barnard study. It wasn't Barnes, it was</p> <p>2 Barnard. And those are both referenced on page</p> <p>3 46 of my report. And then there was also the --</p> <p>4 Hurwitz study. Correct.</p> <p>5 Q. So Wu was in 2009, correct?</p> <p>6 A. Yes.</p> <p>7 Q. Barnard was in 2018. Correct?</p> <p>8 A. Correct.</p> <p>9 Q. And you go on to talk about Trabert</p> <p>10 and Hurwitz.</p> <p>11 A. Correct. And then there's also --</p> <p>12 Q. And --</p> <p>13 A. I'm sorry, there's also the Merritt</p> <p>14 study from 2008.</p> <p>15 Q. And in regard to aspirin in</p> <p>16 particular, both Trabert and Hurwitz report that</p> <p>17 the use of aspirin decreases the risk of ovarian</p> <p>18 cancer. True?</p> <p>19 MS. CURRY: Object to the form.</p> <p>20 THE WITNESS: Actually, only for</p> <p>21 the first ten years of use, and then the</p> <p>22 risk-benefit falls off or was actually</p> <p>23 slightly elevated.</p> <p>24 BY MS. O'DELL:</p>	<p style="text-align: right;">Page 192</p> <p>1 MS. O'DELL: -- 21, the Trabert</p> <p>2 article from 2019.</p> <p>3 (Exhibit No. 21 was marked for</p> <p>4 identification.)</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. And this is an OCAC -- excuse me,</p> <p>7 this is an Ovarian Cancer Cohort Consortium</p> <p>8 study, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And so in other words, this is a</p> <p>11 study that includes data from multiple cohort</p> <p>12 studies that had been -- all the patients had</p> <p>13 been considered together. True?</p> <p>14 A. Correct.</p> <p>15 Q. And it includes as authors on the</p> <p>16 study Dr. Trabert, Dale Sandler, Katie O'Brien,</p> <p>17 Nicholas Wentzensen, and Shelly Tworoger, all of</p> <p>18 whom have published extensively in this area.</p> <p>19 MS. CURRY: Object to the form.</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. Agree?</p> <p>22 A. I am not familiar with the</p> <p>23 public -- with the CVs or publication lists of</p> <p>24 all of those authors.</p>
<p style="text-align: right;">Page 191</p> <p>1 Q. But Trabert, for example, reports a</p> <p>2 10 percent reduction in ovarian cancer for daily</p> <p>3 use of aspirin.</p> <p>4 You actually write that in your</p> <p>5 report. True?</p> <p>6 MS. CURRY: Object to the form.</p> <p>7 THE WITNESS: Right, and that's</p> <p>8 exactly what I wrote, and then I</p> <p>9 finished that sentence. But that was</p> <p>10 only for the first ten years of use,</p> <p>11 after which the benefit was no longer</p> <p>12 there or the actual ratio flips and the</p> <p>13 risk becomes increased. That's --</p> <p>14 that's from Trabert.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. And then Hurwitz reports a 13</p> <p>17 percent reduction of ovarian cancer with the</p> <p>18 frequent use of aspirin. True?</p> <p>19 MS. CURRY: Object to the form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 MS. O'DELL: And I will just</p> <p>22 mark for the record as Exhibit -- am I</p> <p>23 at 22?</p> <p>24 MS. CURRY: 21.</p>	<p style="text-align: right;">Page 193</p> <p>1 Q. Well, having read the literature in</p> <p>2 this area for purposes of this case, you would --</p> <p>3 you recognize these authors, many of the authors</p> <p>4 I just named, true?</p> <p>5 A. Some of them. Not all of them.</p> <p>6 Q. Katie O'Brien is somebody you</p> <p>7 recognize her name, I'm sure.</p> <p>8 A. For sure.</p> <p>9 Q. And if you'll look on page 1 in the</p> <p>10 Introduction on the right-hand side, these</p> <p>11 authors state: "Chronic inflammation likely</p> <p>12 plays a key role in ovarian cancer</p> <p>13 carcinogenesis."</p> <p>14 Did I read that correctly?</p> <p>15 MS. CURRY: I'm sorry, where are</p> <p>16 you?</p> <p>17 THE WITNESS: Oh, right here.</p> <p>18 Yes, you read that correctly.</p> <p>19 BY MS. O'DELL:</p> <p>20 Q. And you disagree with that</p> <p>21 statement. True?</p> <p>22 A. Well, again, they are referencing</p> <p>23 to Ness, which is a hypothesis paper, not</p> <p>24 science. And the authors here actually say</p>

<p style="text-align: right;">Page 194</p> <p>1 "likely," so they qualify it. So I don't think 2 that's a conclusive statement. 3 Q. And if you'll look in the results, 4 Dr. Saenz, and we can look at either results in 5 the abstract or I'm happy to point you to 6 Table 2, but in the results of the abstract, it 7 says: "Women who used aspirin almost daily, 8 greater than six days a week, versus infrequent 9 nonuse, experienced a 10 percent reduction in 10 ovarian cancer risk." Correct? 11 A. Correct, and that's what I cited to 12 in my report. 13 Q. Okay. And despite the fact that 14 both in Trabert and Hurwitz, the use of aspirin, 15 which is a nonsteroidal that reduces 16 inflammation, it's your view that inflammation is 17 not associated with the development of ovarian 18 cancer; is that correct? 19 A. So the studies show that the 20 benefit of aspirin use is not consistent, and in 21 fact, even in this paper, the authors say that 22 they don't understand why more than ten-plus 23 years of use potentially elevates the risk for 24 the development of ovarian cancer.</p>	<p style="text-align: right;">Page 196</p> <p>1 A. Did you say nine or non? Oh, nine. 2 Sorry. Yes, nine. 3 Q. Nine, correct. 4 And eight case-control studies from 5 the Ovarian Cancer Association Consortium with 6 5,726 cases of ovarian cancer, correct? 7 A. Correct. 8 Q. And they go on to say in the 9 conclusion that: "This study is the largest to 10 date on aspirin use and ovarian cancer. It 11 provides evidence that frequent aspirin use is 12 associated with lower ovarian cancer risk 13 regardless of the presence of most other ovarian 14 cancer risk factors." 15 Did I read that correctly? 16 A. Correct. 17 Q. And this was published in 2022. 18 A. Correct. 19 Q. Correct? 20 And this is the most recent 21 publication of aspirin and ovarian cancer, 22 correct? 23 A. I believe so. It's the most recent 24 one I cited to.</p>
<p style="text-align: right;">Page 195</p> <p>1 So the inconsistency in this 2 literature is why I say that there is not 3 consistent evidence that inflammation is 4 developed -- sorry, is associated with the 5 development of ovarian cancer. 6 MS. O'DELL: Okay. And I'm 7 going to mark for the record exhibit -- 8 as Exhibit 22 the Hurwitz paper. 9 Please, Paula. Thank you. 10 (Exhibit No. 22 was marked for 11 identification.) 12 BY MS. O'DELL: 13 Q. And Exhibit 22 is the Hurwitz paper 14 you cite in your report, correct? 15 A. Yes. 16 Q. And this actually is from the 17 Ovarian Cancer Association Consortium or OCAC. 18 True? 19 A. Yes. 20 Q. And it also includes non- -- well, 21 let me just back up. 22 It includes non-cohort studies from 23 the Ovarian Cancer Cohort Consortium of 2,600 24 cases, correct?</p>	<p style="text-align: right;">Page 197</p> <p>1 Q. And in this case, it's the largest, 2 it's the most recent, and it shows a 13 percent 3 reduction of ovarian cancer risk with the use of 4 aspirin. Correct? 5 A. With greater than or equal to six 6 days of use for more than, I think it was, six 7 months. 8 Q. And there's no limitation or any 9 increased risk associated with greater than ten 10 years reported in this -- in the Hurwitz study, 11 correct? 12 A. I don't know how long they followed 13 the women for in this study. I would have to 14 look at that. 15 Q. And if you will turn to page 5 of 16 the paper, the lower right-hand column under 17 Discussion, the last sentence says: "The 18 consistency of frequent aspirin use and ovarian 19 cancer association across the individual 20 case-control and cohort study populations was 21 notable and provides strong support for the 22 beneficial effect of frequent aspirin use on 23 ovarian cancer risk." 24 That was the conclusion of the</p>



<p style="text-align: right;">Page 198</p> <p>1 authors, correct?</p> <p>2 A. Correct. But, I mean, within this</p> <p>3 study they actually found no benefit to reduction</p> <p>4 in risk of endometrioid or clear cell carcinomas,</p> <p>5 which are thought to be associated with</p> <p>6 endometriosis, an inflammatory process.</p> <p>7 And in fact, in the sentence you</p> <p>8 just read, although the authors are summarizing</p> <p>9 what their data -- their results showed, they</p> <p>10 don't have a hypothesis as to why that benefit</p> <p>11 is. So the mechanism is still lacking.</p> <p>12 Q. That's not what they're saying that</p> <p>13 the mechanism -- they don't state in this paper</p> <p>14 that the mechanism is still lacking, do they,</p> <p>15 ma'am?</p> <p>16 A. They don't state that they have</p> <p>17 one.</p> <p>18 Q. No, that's not my question. Do</p> <p>19 they make a statement in this paper that the</p> <p>20 mechanism is lacking in regard to aspirin and</p> <p>21 ovarian cancer?</p> <p>22 A. They don't have a mechanism.</p> <p>23 Q. No, no, no. You just said they</p> <p>24 state the mechanism is lacking.</p>	<p style="text-align: right;">Page 200</p> <p>1 looking at aspirin, which is a nonsteroidal which</p> <p>2 inhibits inflammation. That's the premise of the</p> <p>3 paper.</p> <p>4 A. They say likely, and they cite to</p> <p>5 Ness, which again has no data in it.</p> <p>6 Q. Okay. Let's turn back to page --</p> <p>7 sorry, just a second here -- page 19 of your</p> <p>8 report.</p> <p>9 You begin your section on</p> <p>10 epidemiology, and I want to talk about a couple</p> <p>11 of things. First, page 19, at the bottom of the</p> <p>12 paragraph, you include a statement: "None of the</p> <p>13 studies found an odds ratio of greater than 2</p> <p>14 when looking at never versus ever perineal use of</p> <p>15 talc in ovarian cancer."</p> <p>16 Why did you reference greater than</p> <p>17 2 as a threshold odds ratio?</p> <p>18 A. It's just a fact.</p> <p>19 Q. No, I'm saying why was that</p> <p>20 relevant? Is it your opinion that an odds ratio</p> <p>21 would have to be greater than 2 in order for an</p> <p>22 agent to be causal?</p> <p>23 A. No.</p> <p>24 Q. Is it your opinion that an</p>
<p style="text-align: right;">Page 199</p> <p>1 A. No, I said that --</p> <p>2 Q. That's not included in this paper,</p> <p>3 and that's what I'm trying to establish.</p> <p>4 A. I said they don't describe the</p> <p>5 mechanism and they don't have a hypothesis for</p> <p>6 the mechanism. I said that, they don't list</p> <p>7 that.</p> <p>8 Q. In fact, they do have --</p> <p>9 A. And that's --</p> <p>10 Q. I'm sorry. Please go ahead.</p> <p>11 A. And that's true. Their statement</p> <p>12 just said that with frequent use greater than six</p> <p>13 days per week, more than six months, there is a</p> <p>14 reduction in risk of 13 percent in ovarian</p> <p>15 cancer. But it is perplexing to them because</p> <p>16 they discuss it as to why that benefit was not</p> <p>17 seen with the cancers typically associated with</p> <p>18 endometriosis. So they say there's a reduction</p> <p>19 of risk, but they don't say why.</p> <p>20 Q. And they say at the beginning, the</p> <p>21 whole premise -- and I don't want to rehash this</p> <p>22 because we talked about it before -- on page 1,</p> <p>23 that chronic inflammation likely plays a key role</p> <p>24 in carcinogenesis, and that's the reason they're</p>	<p style="text-align: right;">Page 201</p> <p>1 increased risk of less than 2 can still be</p> <p>2 causal?</p> <p>3 A. Yes.</p> <p>4 Q. What is an example of that?</p> <p>5 A. I believe hormone replacement</p> <p>6 therapy and the risk of developing breast cancer.</p> <p>7 Q. Any others?</p> <p>8 MS. CURRY: Object to the form.</p> <p>9 THE WITNESS: I believe -- I</p> <p>10 don't know across the board, but I</p> <p>11 believe some of the smoking studies had</p> <p>12 an overall risk of less than 2, but the</p> <p>13 literature was consistent.</p> <p>14 BY MS. O'DELL:</p> <p>15 Q. And that was with lung cancer?</p> <p>16 A. Yes, ma'am.</p> <p>17 Q. At page 21, if you will turn there,</p> <p>18 please. You include in your table of</p> <p>19 case-control studies Davis 2021.</p> <p>20 MS. O'DELL: And I'm going to</p> <p>21 mark for the record Davis. I don't have</p> <p>22 a lot of questions on it, but I do want</p> <p>23 to ask you one in particular. And I</p> <p>24 think it's Exhibit 23.</p>

<p style="text-align: right;">Page 202</p> <p>1 (Exhibit No. 23 was marked for 2 identification.) 3 THE WITNESS: Thank you. 4 BY MS. O'DELL: 5 Q. Do you have it? 6 A. Yes, ma'am. 7 Q. And you list Davis as a 8 case-control study. 9 A. Yes. 10 Q. And if you will look on page 23 -- 11 excuse me, Exhibit 23, the first page -- this is 12 -- I guess I'll just ask the question: This is a 13 pooled analysis, not a case-control analysis, is 14 it not, Dr. Saenz? 15 A. It's set up as a case-control 16 study. 17 Q. But it's a combination of data from 18 a series of studies -- of studies that are listed 19 in Table 1. True? 20 A. Right. But, I mean, much like 21 Terry was a pooled analysis of case-control 22 studies, this is the same sort of thing. 23 Q. This is a pooled analysis. This is 24 not a single case-control study.</p>	<p style="text-align: right;">Page 204</p> <p>1 A. Oh, sorry. 2 Q. See that? "For ever use of genital 3 talc was associated with a higher odds ratio of 4 ovarian cancer among African American women, OR 5 of 1.22" -- do you see that? 6 A. Yes. 7 Q. -- "confidence interval of 0.97 to 8 1.53, and white women of 1.36 with a confidence 9 interval of 1.19 to 1.57." 10 Did I read that correctly? 11 A. Yes. 12 Q. And that's for all -- that data was 13 for all epithelial ovarian cancer. True? 14 A. I believe so. 15 Q. And then when they focused on high 16 grade serous tumors, then for African American 17 women there was a slightly increased risk of 1.31 18 that was -- had a confidence interval of 1.01 to 19 1.71, and then for white women -- sorry, I'm not 20 sure I read that right. Yeah, let me just stop 21 there. 22 In African American women, there 23 was -- positive association with risk was more 24 pronounced among high grade serous tumors of</p>
<p style="text-align: right;">Page 203</p> <p>1 MS. CURRY: Object to the form. 2 THE WITNESS: Multiple studies 3 contributed patients to this data, 4 correct. 5 BY MS. O'DELL: 6 Q. Okay. And so it's not a pooled 7 analysis -- I mean, it's a pooled analysis like 8 Terry. It's not a case-control study like, you 9 know, Wu 2015. 10 A. Well, it's not one individual study 11 database, but it is a case-control analysis with 12 the data coming from several different sources. 13 Q. It's a pooled analysis from several 14 different case-control studies. 15 A. Okay, I'll agree with that. 16 Q. And it shows -- it reports for 17 women, both white women and women of -- African 18 American women, a point estimate that shows an 19 increased risk. True? 20 A. Where are we now? 21 Q. Look in Results. 22 A. Oh, we're in the abstract? 23 Q. Yes. That's just an easy place to 24 get the data.</p>	<p style="text-align: right;">Page 205</p> <p>1 1.31, confidence interval of 1.01 to 1.47, 2 correct? 3 A. Correct. Wait, one -- no, that's 4 -- 5 MS. CURRY: Object to the form. 6 THE WITNESS: No, that's not 7 right. No. 8 BY MS. O'DELL: 9 Q. I didn't intend to read that 10 incorrectly, so tell me what I said that was 11 misstated. 12 A. You flipped to the confidence 13 interval for other histotypes. 14 Q. Okay. Let me try again. "More 15 pronounced among high grade serous tumors, OR of 16 1.31, with a confidence interval of 1.01 to 17 1.71." 18 A. That's correct. 19 Q. You note in your report in several 20 places in regard to the data study, they fail to 21 demonstrate a clear dose-response. Do you recall 22 those statements? 23 A. Yes. 24 Q. And I ask you to turn to the next</p>

<p style="text-align: right;">Page 206</p> <p>1 to the last page of the study.</p> <p>2 Let me know when you're there.</p> <p>3 A. I'm there.</p> <p>4 Q. And this is the Discussion section.</p> <p>5 And on the left-hand side, midway down there's a</p> <p>6 sentence that begins "We did not conduct." Do</p> <p>7 you see that?</p> <p>8 A. Not yet.</p> <p>9 Q. Left-hand side, midway down, end of</p> <p>10 the first full paragraph. "We did not conduct an</p> <p>11 analysis."</p> <p>12 A. Okay.</p> <p>13 Q. Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. "We did not conduct an analysis</p> <p>16 that addressed both duration and frequency of</p> <p>17 application. Some women may use body powder</p> <p>18 products on a daily -- non-daily basis.</p> <p>19 Therefore, the best measure of dose may be number</p> <p>20 of applications based on frequency of application</p> <p>21 times years of use. However, this measure was</p> <p>22 not available for most OCWAA studies."</p> <p>23 Did I read that correctly?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 208</p> <p>1 30 of your report.</p> <p>2 And at the bottom of page 30, it</p> <p>3 begins your discussion of the O'Brien pooled</p> <p>4 analysis of the cohort studies. Correct?</p> <p>5 A. I'm there.</p> <p>6 MS. O'DELL: And I want to go</p> <p>7 ahead and mark for the record O'Brien as</p> <p>8 Exhibit No. -- the O'Brien 2020 study as</p> <p>9 Exhibit 23.</p> <p>10 MS. CURRY: 24.</p> <p>11 MS. O'DELL: Thank you.</p> <p>12 (Exhibit No. 24 was marked for</p> <p>13 identification.)</p> <p>14 BY MS. O'DELL:</p> <p>15 Q. Do you have it?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. This was published in</p> <p>18 January of 2020 in JAMA, and it was a pooled</p> <p>19 analysis of the data from the cohort studies,</p> <p>20 correct?</p> <p>21 A. Yes, with the addition of the</p> <p>22 NHS-II study, yes.</p> <p>23 Q. And if you will turn to Table 1,</p> <p>24 the number of ovarian cancers included was 2,213,</p>
<p style="text-align: right;">Page 207</p> <p>1 Q. And that can be one reason that a</p> <p>2 clear dose-response was not seen in the study.</p> <p>3 True?</p> <p>4 MS. CURRY: Object to the form.</p> <p>5 THE WITNESS: Well --</p> <p>6 BY MS. O'DELL:</p> <p>7 Q. That's true?</p> <p>8 A. Well, that could be. But my</p> <p>9 comments as pertains to a lack of dose-response</p> <p>10 being demonstrated by the Davis article really</p> <p>11 have to do with the fact that African American</p> <p>12 women used far more perineal talc than Caucasian</p> <p>13 women, and yet they did not show the same</p> <p>14 statistically significant increased risk as the</p> <p>15 women that used less.</p> <p>16 Q. And isn't it true in African</p> <p>17 American women, you're likely to see a greater</p> <p>18 number of pregnancies in African American women</p> <p>19 than you are with white women in these studies?</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 THE WITNESS: I have no idea to</p> <p>22 substantiate that statement.</p> <p>23 BY MS. O'DELL:</p> <p>24 Q. Turn if you would, please, to page</p>	<p style="text-align: right;">Page 209</p> <p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And they reported -- looking at</p> <p>4 Table 2, for ever use used talc in the genital</p> <p>5 area, all women, a pooled estimate -- this is all</p> <p>6 women -- of 1.08 and confidence interval .99 to</p> <p>7 1.17.</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes.</p> <p>10 Q. And is it your opinion, Dr. Saenz,</p> <p>11 that the fact that the confidence interval</p> <p>12 crosses 1 means there's no association?</p> <p>13 A. It means that that finding is not</p> <p>14 statistically significant.</p> <p>15 Q. And would you agree with me that</p> <p>16 they demonstrated an increased risk?</p> <p>17 MS. CURRY: Object to the form.</p> <p>18 THE WITNESS: No, I don't agree</p> <p>19 with you -- with that. You have a</p> <p>20 hazard ratio that is 1.08, but that is</p> <p>21 not statistically significant, which</p> <p>22 means that those findings could be due</p> <p>23 to chance, confounding, biases. It's</p> <p>24 not statistically significant.</p>

<p style="text-align: right;">Page 210</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. And therefore, in your view, it</p> <p>3 means there's no association?</p> <p>4 A. In my view, they have not</p> <p>5 demonstrated an increased risk with the use of</p> <p>6 talc.</p> <p>7 Q. And for the data for women with</p> <p>8 patent reproductive tracts, the pooled estimate</p> <p>9 for ever versus never is 1.13 with a confidence</p> <p>10 interval of 1.01 to 1.26, correct?</p> <p>11 A. That's what they reported.</p> <p>12 Q. And so they have in that instance</p> <p>13 demonstrated an increased risk of ovarian cancer</p> <p>14 with genital talc use, correct?</p> <p>15 MS. CURRY: Object to the form.</p> <p>16 THE WITNESS: They reported that</p> <p>17 hazard ratio, but when you compare that</p> <p>18 group to the women with non-patent</p> <p>19 reproductive tract, they're not</p> <p>20 different study populations. So I don't</p> <p>21 think that particular statistic has any</p> <p>22 meaning.</p> <p>23 BY MS. O'DELL:</p> <p>24 Q. And so despite the fact that it</p>	<p style="text-align: right;">Page 212</p> <p>1 application of talc during those 20 years from</p> <p>2 their teens to 35 or 40 years old is the exact</p> <p>3 same in those two study populations. The</p> <p>4 intervention, if you will, of a tubal ligation</p> <p>5 does not happen until women have already been</p> <p>6 exposed for 20-plus years.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. And that assumes that talc enters</p> <p>9 the vagina and can reach the ovaries, correct?</p> <p>10 MS. CURRY: Object to the form.</p> <p>11 THE WITNESS: Well, that's the</p> <p>12 hypothesis of why there would be a</p> <p>13 difference between -- in exposure</p> <p>14 between women with tubal ligations</p> <p>15 versus women without tubal ligations,</p> <p>16 but the actual data as to when women are</p> <p>17 using the talc does not at all correlate</p> <p>18 with when women get tubal ligations.</p> <p>19 BY MS. O'DELL:</p> <p>20 Q. We can go through it all, but you</p> <p>21 would agree with me that when they looked at</p> <p>22 greater than or equal to one time a week for both</p> <p>23 all women and for women with patent reproductive</p> <p>24 tracts, the study demonstrated an increased risk.</p>
<p style="text-align: right;">Page 211</p> <p>1 shows a 1.13 odds ratio, you feel that that has</p> <p>2 no meaning and no relevance to the question of</p> <p>3 whether talc can cause ovarian cancer?</p> <p>4 MS. CURRY: Object to the form.</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. That's what you just said, it has</p> <p>7 no meaning.</p> <p>8 A. I think -- I think what has no</p> <p>9 meaning to the -- and no relevance to the</p> <p>10 development of ovarian cancer is to pull out</p> <p>11 women that have patent reproductive tracts from</p> <p>12 women that do not, because they are not different</p> <p>13 study populations. Women start --</p> <p>14 Q. Well -- I'm sorry, ma'am. What's</p> <p>15 your basis for saying that, just so I can</p> <p>16 understand better what you're --</p> <p>17 A. Women start using talc in their 20s</p> <p>18 -- in their teens or in their 20s, and they use</p> <p>19 it on average, according to Cramer, for 20-plus</p> <p>20 years.</p> <p>21 Women do not have tubal ligations</p> <p>22 until they are done having their children, which</p> <p>23 is usually in their 30s or 40s.</p> <p>24 So the exposure per se to perineal</p>	<p style="text-align: right;">Page 213</p> <p>1 MS. CURRY: Object to the form.</p> <p>2 THE WITNESS: The authors</p> <p>3 reported an increased risk in women that</p> <p>4 they pulled out that had patent</p> <p>5 reproductive tracts, but it's not a</p> <p>6 meaningful piece of data.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. And they report a 9 percent or 1.09</p> <p>9 adjusted hazard ratio for all women who used talc</p> <p>10 at least once a week. True?</p> <p>11 MS. CURRY: Where are you</p> <p>12 reading from, Leigh? Which table is</p> <p>13 that?</p> <p>14 MS. O'DELL: Table 3.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. Look at Table 3, Dr. Saenz, in the</p> <p>17 top half.</p> <p>18 A. I'm getting there. Table 3, top</p> <p>19 half.</p> <p>20 Q. I'm looking at "used powder greater</p> <p>21 or equal to one time a week."</p> <p>22 A. Right.</p> <p>23 Q. And --</p> <p>24 A. With the adjusted HR of 1.09?</p>

<p style="text-align: right;">Page 214</p> <p>1 Q. Correct.</p> <p>2 A. Right. So that was not</p> <p>3 statistically significant.</p> <p>4 Q. And therefore, you believe that is</p> <p>5 not demonstrating an increased risk. True?</p> <p>6 A. Correct.</p> <p>7 Q. You state in your report on page 31</p> <p>8 that -- in the second paragraph on page 31: "It</p> <p>9 is notable that plaintiff's experts seek to</p> <p>10 assign essentially zero weight to the O'Brien</p> <p>11 study based on perceived weaknesses of the</p> <p>12 study."</p> <p>13 A. I'm sorry, I'm not -- I -- are</p> <p>14 we -- where are we?</p> <p>15 MS. CURRY: Your report here --</p> <p>16 THE WITNESS: Oh, down here.</p> <p>17 Okay, sorry.</p> <p>18 I'm there now. Okay, go ahead.</p> <p>19 BY MS. O'DELL:</p> <p>20 Q. You say: "It is notable that</p> <p>21 plaintiff's experts seek to assign essentially</p> <p>22 zero weight to the O'Brien study based on</p> <p>23 perceived weaknesses of the study."</p> <p>24 What's your basis for saying that?</p>	<p style="text-align: right;">Page 216</p> <p>1 that because they cite the letters to the editor</p> <p>2 that were submitted by Drs. Cramer, Rothman,</p> <p>3 Harlow and others, that they discounted the</p> <p>4 relevance of the O'Brien study. Is that what</p> <p>5 you're saying?</p> <p>6 A. That and they wrote that they</p> <p>7 agreed with those criticisms.</p> <p>8 Q. Did they misstate the data from</p> <p>9 O'Brien in any way in their reports?</p> <p>10 A. Not that I'm aware of.</p> <p>11 Q. Did they state in any respect that</p> <p>12 they did not consider O'Brien fully and fairly in</p> <p>13 reaching their expert opinions?</p> <p>14 MS. CURRY: Object to the form.</p> <p>15 THE WITNESS: They did comment</p> <p>16 on the fact that they thought that</p> <p>17 O'Brien didn't -- wasn't sufficiently</p> <p>18 powered in order to have a positive</p> <p>19 finding, and I believe that that's</p> <p>20 incorrect.</p> <p>21 MS. O'DELL: Let's mark as</p> <p>22 Exhibit 25 the letters to the editor.</p> <p>23 It should just be letters to the</p> <p>24 editor, Paula, in the box as Exhibit 25.</p>
<p style="text-align: right;">Page 215</p> <p>1 A. When I read Dr. Clarke-Pearson and</p> <p>2 Dr. Wolf's analysis of the O'Brien study in their</p> <p>3 reports.</p> <p>4 Q. They don't refer to weight in</p> <p>5 either of their reports, correct?</p> <p>6 A. You mean weight as a measure -- I</p> <p>7 mean, that's my colloquial term for them</p> <p>8 discussing whether or not this study is relevant.</p> <p>9 It's not a weighted analysis.</p> <p>10 Q. Well, exactly. You don't have any</p> <p>11 insight as to what weight they put on the study</p> <p>12 or didn't put on the study, do you?</p> <p>13 MS. CURRY: Object to the form.</p> <p>14 THE WITNESS: Actually, I do,</p> <p>15 because they quoted in their reports the</p> <p>16 published criticisms of the O'Brien</p> <p>17 paper saying that it was not a good</p> <p>18 study for the reasons outlined by --</p> <p>19 just above where you're reading from,</p> <p>20 the commentary from Drs. Cramer, Harlow,</p> <p>21 Murray and Rothman. So that was cited</p> <p>22 to by Drs. Clarke- Pearson and Wolf.</p> <p>23 BY MS. O'DELL:</p> <p>24 Q. And you -- you -- it's your opinion</p>	<p style="text-align: right;">Page 217</p> <p>1 (Exhibit No. 25 was marked for</p> <p>2 identification.)</p> <p>3 BY MS. O'DELL:</p> <p>4 Q. You've seen this before, haven't</p> <p>5 you, Dr. Saenz?</p> <p>6 A. Yes, ma'am.</p> <p>7 Q. And these were letters to the</p> <p>8 editors that were submitted to JAMA in relation</p> <p>9 to the O'Brien paper, O'Brien 2020 paper, and</p> <p>10 Dr. O'Brien and Dr. Sandler and Dr. Wentzensen</p> <p>11 replied to the comments that were made by the</p> <p>12 researchers who wrote in, correct? They -- they</p> <p>13 replied.</p> <p>14 A. Yes.</p> <p>15 Q. If you will turn to page 2097.</p> <p>16 A. Yes.</p> <p>17 Q. Dr. O'Brien and others replies to</p> <p>18 Dr. Rothman and Harlow's concern about the way</p> <p>19 Dr. O'Brien and others had addressed statistical</p> <p>20 significance in the study, correct?</p> <p>21 MS. CURRY: Object to the form.</p> <p>22 THE WITNESS: Can you direct me</p> <p>23 to where you are exactly?</p> <p>24 BY MS. O'DELL:</p>



<p style="text-align: right;">Page 218</p> <p>1 Q. I would be happy to do that.</p> <p>2 And let me just go back a page.</p> <p>3 Maybe it will make this easier for you and for</p> <p>4 all of us.</p> <p>5 Go back to page 2096, Dr. Harlow,</p> <p>6 Murray and Rothman in their last paragraph</p> <p>7 states: "To conclude that there is," quote, "no</p> <p>8 statistical significant association based on an</p> <p>9 HR of 1.08, 95 percent confidence interval 0.99</p> <p>10 to 1.17, is now recognized as poor practice in</p> <p>11 population in clinical research. If the 99</p> <p>12 percent CI had instead been 1.01 to 1.19, would</p> <p>13 the authors have had a completely different</p> <p>14 interpretation? Given that the authors</p> <p>15 produced -- reported a 13 percent increased risk</p> <p>16 of ovarian cancer among women with intact genital</p> <p>17 tracts who used powder despite these</p> <p>18 methodological issues, this study should have</p> <p>19 been taken as evidence of an effect."</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes, except that you read 99</p> <p>22 percent CI when it's 95, but you don't have to</p> <p>23 reread it.</p> <p>24 Q. Thank you. You disagree with that</p>	<p style="text-align: right;">Page 220</p> <p>1 of those authors, but I do disagree with</p> <p>2 their contention that statistical</p> <p>3 significance should be thrown out the</p> <p>4 window.</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. That's not what they say, to be</p> <p>7 fair.</p> <p>8 A. Yes, they say that we should not be</p> <p>9 paying attention to confidence intervals, and I</p> <p>10 disagree with that.</p> <p>11 Q. Well, you disagree with Dr. O'Brien</p> <p>12 as well. True?</p> <p>13 MS. CURRY: Object to the form.</p> <p>14 THE WITNESS: I disagree with</p> <p>15 Dr. O'Brien that the women with patent</p> <p>16 reproductive tracts have had a different</p> <p>17 exposure history with respect to the</p> <p>18 perineal application of talc than the</p> <p>19 women with non-patent reproductive</p> <p>20 tracts.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. And you disagree with her regarding</p> <p>23 statistical significance. True?</p> <p>24 MS. CURRY: Object to the form.</p>
<p style="text-align: right;">Page 219</p> <p>1 statement from -- those statements from Rothman,</p> <p>2 Harlow and Murray, correct?</p> <p>3 A. I do. We, by convention, do not</p> <p>4 throw out the concept of statistical significance</p> <p>5 in analyzing data.</p> <p>6 Q. And you talk in your report about</p> <p>7 statistically unsophisticated readers, and you</p> <p>8 refer to statistically unsophisticated readers on</p> <p>9 page 32 of your report.</p> <p>10 A. Well, I quote --</p> <p>11 MS. CURRY: Object to the form.</p> <p>12 THE WITNESS: Sorry. I quote</p> <p>13 another editorial on this article.</p> <p>14 BY MS. O'DELL:</p> <p>15 Q. And she -- but you quote</p> <p>16 "statistically unsophisticated readers." True?</p> <p>17 A. Yes, that's the quote.</p> <p>18 Q. And is it your view that</p> <p>19 Dr. Rothman, Harlow and Murray are statistically</p> <p>20 unsophisticated readers?</p> <p>21 MS. CURRY: Object to the form.</p> <p>22 THE WITNESS: I'm just quoting</p> <p>23 what that other editorial said. I'm not</p> <p>24 commenting on the sophistication or not</p>	<p style="text-align: right;">Page 221</p> <p>1 THE WITNESS: Can you direct me</p> <p>2 to what you're talking about?</p> <p>3 BY MS. O'DELL:</p> <p>4 Q. Yes. Next page, left-hand column,</p> <p>5 the paragraph beginning "We completely agree."</p> <p>6 Do you see that?</p> <p>7 Dr. O'Brien and others write: "We</p> <p>8 completely agree with Dr. Harlow and colleagues</p> <p>9 that our results, particularly the analyses</p> <p>10 limited to women with intact reproductive tracts,</p> <p>11 should not be discounted because of lack of</p> <p>12 statistical significance."</p> <p>13 So you disagree with Dr. O'Brien.</p> <p>14 A. Yes.</p> <p>15 Q. True?</p> <p>16 A. With respect to that, yes.</p> <p>17 Q. "For all estimates, we reported 95</p> <p>18 percent CIs so readers could consider the effect,</p> <p>19 size and precision. The qualifier that there was</p> <p>20 no statistically significant association between</p> <p>21 ever genital powder use and ovarian cancer is a</p> <p>22 factual report of the test of the null</p> <p>23 hypothesis. We never equated the lack of</p> <p>24 statistical significance to evidence -- to</p>

<p style="text-align: right;">Page 222</p> <p>1 evidence of no association."</p> <p>2 Did I read that correctly?</p> <p>3 A. Yes, you did.</p> <p>4 Q. In the O'Brien paper as well, the</p> <p>5 authors also -- in addition to reporting the data</p> <p>6 on the study, also talk about talc by irritating</p> <p>7 epithelial ovarian tissue and fallopian tubes</p> <p>8 directly, the powder could induce an inflammatory</p> <p>9 response even in the absence of asbestos."</p> <p>10 MS. CURRY: Where are you</p> <p>11 reading?</p> <p>12 BY MS. O'DELL:</p> <p>13 Q. Do you recall that?</p> <p>14 MS. CURRY: What page is that?</p> <p>15 MS. O'DELL: It's on page 56.</p> <p>16 THE WITNESS: There's no data</p> <p>17 for that.</p> <p>18 BY MS. O'DELL:</p> <p>19 Q. Do you see where I'm reading,</p> <p>20 ma'am?</p> <p>21 A. Yes, I do.</p> <p>22 Q. And that's what they state,</p> <p>23 correct?</p> <p>24 A. They do state that, but there's no</p>	<p style="text-align: right;">Page 224</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. And I want to talk about Woolen,</p> <p>3 and specifically the purpose of Woolen to</p> <p>4 evaluate frequent use of talc.</p> <p>5 Ms. Converse, Dr. Saenz, would have</p> <p>6 been a frequent user of talc, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And in the Woolen paper, "frequent</p> <p>9 use" was defined as two or more times a week,</p> <p>10 correct?</p> <p>11 MS. CURRY: Object to the form.</p> <p>12 THE WITNESS: I think the</p> <p>13 authors defined it as at least two times</p> <p>14 per week.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. Yeah. And if you'll look on page 2</p> <p>17 of the study, and they say multiple --</p> <p>18 A. I'm sorry, what -- what section are</p> <p>19 you on?</p> <p>20 Q. Page 2 of the study, "Eligibility</p> <p>21 Criteria and Study Selection."</p> <p>22 A. Got it.</p> <p>23 Q. Second sentence.</p> <p>24 A. Okay.</p>
<p style="text-align: right;">Page 223</p> <p>1 data for that.</p> <p>2 Q. They go on to say: "This could set</p> <p>3 off a cascade of increased oxidative stress</p> <p>4 levels, DNA damage, a cell division, all of which</p> <p>5 could contribute to carcinogenesis."</p> <p>6 Do you see that?</p> <p>7 A. Again -- yes, that's a hypothesis,</p> <p>8 and again, they're citing to Ness once again,</p> <p>9 which is a summary article with hypotheses and no</p> <p>10 data.</p> <p>11 MS. O'DELL: All right. Let's</p> <p>12 go off the record, please.</p> <p>13 (Recess.)</p> <p>14 MS. O'DELL: Okay. Let's go</p> <p>15 back on the record.</p> <p>16 BY MS. O'DELL:</p> <p>17 Q. Let me direct your attention back</p> <p>18 to page 32, and you discuss Woolen 2023.</p> <p>19 A. 2022.</p> <p>20 Q. Excuse me, yes, the 2022 paper.</p> <p>21 MS. O'DELL: And I'm going to</p> <p>22 mark that as Exhibit 26.</p> <p>23 (Exhibit No. 26 was marked for</p> <p>24 identification.)</p>	<p style="text-align: right;">Page 225</p> <p>1 Q. They reported primary data on</p> <p>2 "frequent" defined as multiple, two or more times</p> <p>3 per week, perineal exposure to talc.</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. And Ms. Converse used daily, so she</p> <p>7 would be in that frequent user group, correct?</p> <p>8 A. Yes.</p> <p>9 Q. And for this Woolen study, it was a</p> <p>10 meta-analysis of ten case-control studies and</p> <p>11 data from one cohort study. Correct?</p> <p>12 A. With -- right, data from one cohort</p> <p>13 study with additional data that was requested</p> <p>14 from the authors.</p> <p>15 Q. In fact, that's -- you're going to</p> <p>16 where I wanted to ask. You state in your report:</p> <p>17 "One cohort study which they claim is O'Brien</p> <p>18 2020, but in fact, it's actually only data from</p> <p>19 Nurses' Health Study I with inclusion of</p> <p>20 previously unpublished data."</p> <p>21 Do you see that in your report?</p> <p>22 A. Yes.</p> <p>23 Q. And if you will look at Table 2 of</p> <p>24 the study, it lists the publications included in</p>

<p style="text-align: right;">Page 226</p> <p>1 the systematic review.</p> <p>2 A. Correct.</p> <p>3 Q. And they extract data from these</p> <p>4 studies that is the most frequent perineal talcum</p> <p>5 powder use reported for each study. Correct?</p> <p>6 A. Well, what they actually did was if</p> <p>7 the data was reported in more than one study,</p> <p>8 they used the study that reported the higher use.</p> <p>9 Q. I don't think we're communicating.</p> <p>10 Because from the each individual study, they</p> <p>11 extracted data that was the most -- that reported</p> <p>12 the most frequent perineal talc use.</p> <p>13 MS. CURRY: Object to the form,</p> <p>14 asked and answered.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. Correct?</p> <p>17 A. So the authors say that in area --</p> <p>18 or in some -- in the sections where duplicate</p> <p>19 reports of the same study subjects were</p> <p>20 published, they did not use the subject report or</p> <p>21 that data if it was a lower usage. So -- because</p> <p>22 in some of these studies, the subjects</p> <p>23 overlapped.</p> <p>24 Q. I understand.</p>	<p style="text-align: right;">Page 228</p> <p>1 it? It says "O'Brien," paren, "NHS-I." Correct?</p> <p>2 A. No, it says 2020 right there. If</p> <p>3 you go over to year, the column year, it says</p> <p>4 2020.</p> <p>5 Q. Look at the first author, just so</p> <p>6 you'll --</p> <p>7 A. What?</p> <p>8 Q. It says O'Brien "NHS-I" in the</p> <p>9 first column under first author.</p> <p>10 A. Right.</p> <p>11 Q. All right, bear with me. Look</p> <p>12 at -- there's a -- there's a notation of a</p> <p>13 reference at the bottom, a footnote. Do you see</p> <p>14 that? It's actually number 5. Do you see</p> <p>15 number 5 after the paren?</p> <p>16 A. Yes.</p> <p>17 Q. Go to the bottom of the table, and</p> <p>18 it says: "O'Brien did not publish on daily</p> <p>19 exposure for the National Health Study</p> <p>20 participants. However, these data were</p> <p>21 available, and O'Brien provided these data for</p> <p>22 inclusion. The entirety of the data were</p> <p>23 provided and are shared in the supplemental</p> <p>24 table. We include data on women with intact</p>
<p style="text-align: right;">Page 227</p> <p>1 And so their design was that they</p> <p>2 would extract the data from the most exposed</p> <p>3 group. In other words, the most frequent use</p> <p>4 data is what they extracted from each study.</p> <p>5 Correct?</p> <p>6 A. Right. If they had a choice for</p> <p>7 similar study subjects of a lower exposure versus</p> <p>8 a higher exposure, they did not use the data from</p> <p>9 the lower exposure.</p> <p>10 Q. They used the data from the higher</p> <p>11 exposure.</p> <p>12 A. Even though it was the same study</p> <p>13 subjects, correct.</p> <p>14 Q. Correct, because she</p> <p>15 double-counted. So they used the higher</p> <p>16 exposure, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And in fact, that's what they say</p> <p>19 at the title of Table 2, that they would use the</p> <p>20 most frequent perineal talcum powder use for each</p> <p>21 study. That's what they describe, correct?</p> <p>22 A. Correct.</p> <p>23 Q. And if you look at O'Brien, number</p> <p>24 11 in Table 2, it doesn't say O'Brien 2020, does</p>	<p style="text-align: right;">Page 229</p> <p>1 fallopian tubes to harmonize with other</p> <p>2 publications."</p> <p>3 Did I read that correctly?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And the data from O'Brien</p> <p>6 that they obtained from O'Brien was from Nurses'</p> <p>7 Health Study I, correct?</p> <p>8 A. Well, not -- they didn't obtain all</p> <p>9 of that from O'Brien, right. They already had</p> <p>10 data on Nurses' Health Study I, and they</p> <p>11 augmented it with O'Brien's additional data.</p> <p>12 Q. No, ma'am, if you will look on page</p> <p>13 2 of the study, that's incorrect. If you look on</p> <p>14 page 2 of the study, right-hand column, the</p> <p>15 second -- third sentence down at the first</p> <p>16 paragraph, do you see where it says, "As is</p> <p>17 standard in systematic reviews" --</p> <p>18 A. Yes.</p> <p>19 Q. Do you see that sentence?</p> <p>20 A. Yes.</p> <p>21 Q. -- "to include relevant but</p> <p>22 unpublished results, we contacted O'Brien and</p> <p>23 requested primary data from the Nurses' Health</p> <p>24 Study I (NHS-I) and the Sister Study (SIS) for</p>

<p style="text-align: right;">Page 230</p> <p>1 the highest frequency talc exposure group. The</p> <p>2 data from NHS-I were provided and described in</p> <p>3 the Supplemental Table 1 and are included in a</p> <p>4 systematic review. The data from the SIS study</p> <p>5 were not provided to us due to the small sample</p> <p>6 size of exposed individuals in the highest</p> <p>7 exposure category (n=2 women)."</p> <p>8 Did I read that correctly?</p> <p>9 A. You read that, but these are the</p> <p>10 study subjects from NHS-I. They are the women</p> <p>11 that were originally published in that study.</p> <p>12 And then they went back to O'Brien and asked her</p> <p>13 for the primary data. So it is --</p> <p>14 Q. Well, they asked -- they did not</p> <p>15 include in their meta-analysis data from the</p> <p>16 publication of pooled study O'Brien 2020.</p> <p>17 You're aware of that, aren't you?</p> <p>18 A. That's correct. This is data from</p> <p>19 the NHS-I study that was published before but</p> <p>20 then augmented by the data they got from O'Brien.</p> <p>21 Q. And I just want to make clear, the</p> <p>22 JAMA publication of O'Brien of the pooled</p> <p>23 analysis of cohort study data is not data that's</p> <p>24 included in the Woolen meta-analysis.</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. Correct.</p> <p>2 A. Yes.</p> <p>3 Q. And -- and you -- strike that.</p> <p>4 This meta-analysis, the actual</p> <p>5 combined pooled estimate from this</p> <p>6 meta-analysis -- and I'll just invite you, if you</p> <p>7 want to, to turn over to page -- the next page,</p> <p>8 Figure 2, to make it efficient -- the combined</p> <p>9 pooled summary odds ratio for this meta-analysis</p> <p>10 is 1.47, 95 percent confidence interval, 1.31,</p> <p>11 1.65. Correct?</p> <p>12 A. Correct.</p> <p>13 Q. And that is demonstrating a 47</p> <p>14 percent increased risk, correct?</p> <p>15 MS. CURRY: Object to the form.</p> <p>16 THE WITNESS: Over background</p> <p>17 population risk, correct.</p> <p>18 BY MS. O'DELL:</p> <p>19 Q. And on page 33 of your report, you</p> <p>20 state: "The authors report a summary pooled OR</p> <p>21 of 1.47," which we just discussed, "for all ten</p> <p>22 studies and an OR of 1.49, 1.29 to 1.72, when the</p> <p>23 analysis is restricted to case-control studies.</p> <p>24 This means the positive OR reported in the study</p>
<p style="text-align: right;">Page 231</p> <p>1 A. For the NHS-I part of that pooled</p> <p>2 analysis, it is the same study population.</p> <p>3 Q. That's not my question. Because,</p> <p>4 as you -- you know so well, the O'Brien 2020</p> <p>5 publication did not include data from daily use.</p> <p>6 Correct?</p> <p>7 A. It was ever/ever for most patients.</p> <p>8 So it wasn't data on individual days of use, that</p> <p>9 is correct.</p> <p>10 Q. And the data that's actually</p> <p>11 included in Woolen is the daily exposure data</p> <p>12 from Nurses' Health Study participants, which as</p> <p>13 she -- as described in the footnote, had not been</p> <p>14 previously published.</p> <p>15 Do you see that?</p> <p>16 A. The data on the frequency of use</p> <p>17 was not published, but it is the same study</p> <p>18 subjects as was previously published on. It's</p> <p>19 not new women.</p> <p>20 Q. I'm not saying they're new women.</p> <p>21 I'm saying the data is new because this data had</p> <p>22 never before been published on daily exposure.</p> <p>23 A. It was -- I mean, it was supplied</p> <p>24 to Woolen by O'Brien. So yes.</p>	<p style="text-align: right;">Page 233</p> <p>1 is entirely due to the case-control studies, and</p> <p>2 not at all a reflection of the data contributed</p> <p>3 by Nurses' Health Study I cohort study."</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. What is the increased risk of women</p> <p>7 who daily used talc in Nurses' Health Study I?</p> <p>8 A. In the data from the study?</p> <p>9 Q. In the data as supplied by O'Brien,</p> <p>10 yes.</p> <p>11 A. I would have to look through the</p> <p>12 paper to find that.</p> <p>13 Q. Okay.</p> <p>14 A. But when the Nurses' Health Study I</p> <p>15 is pulled out, the -- the pooled odds ratio</p> <p>16 actually goes up, which means that the Nurses</p> <p>17 Health Study I data was moving it down to 1.47.</p> <p>18 Q. Well, let's be clear, you don't say</p> <p>19 it moved it down. You say: "This means that the</p> <p>20 positive OR reported in this study is entirely</p> <p>21 due to the case-control studies and not at all a</p> <p>22 reflection of the data contributed by the Nurses'</p> <p>23 Health Study I cohort study."</p> <p>24 A. Right.</p>

<p style="text-align: right;">Page 234</p> <p>1 Q. That's what you state.</p> <p>2 A. That's correct.</p> <p>3 Q. But look at supplemental Table 1,</p> <p>4 Dr. Saenz. It should be included in your copy.</p> <p>5 A. It's not.</p> <p>6 Q. Okay.</p> <p>7 MS. BROWN: It should be there.</p> <p>8 Is it --</p> <p>9 MS. CURRY: It's right here.</p> <p>10 BY MS. O'DELL:</p> <p>11 Q. Yep, Table 1 at the end,</p> <p>12 supplemental Table 1.</p> <p>13 MS. CURRY: Oh, that's odd.</p> <p>14 She -- in the marked copy -- the marked</p> <p>15 copy is different than the copy that I</p> <p>16 have, so we should swap the sticker out.</p> <p>17 MS. O'DELL: I'm sorry. I don't</p> <p>18 know the issue there, but --</p> <p>19 MS. CURRY: So Dr. Saenz's copy</p> <p>20 ends after the references, and none of</p> <p>21 the supplemental material are attached</p> <p>22 on the version that was marked as an</p> <p>23 exhibit.</p> <p>24 MS. O'DELL: Okay.</p>	<p style="text-align: right;">Page 236</p> <p>1 A. Yes.</p> <p>2 Q. And the table reports a -- for all</p> <p>3 women daily users. Do you see that --</p> <p>4 A. Yes.</p> <p>5 Q. -- the adjusted hazard ratio --</p> <p>6 A. Yes.</p> <p>7 Q. -- of 1.27, and it's statistically</p> <p>8 significant, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And for women with patent fallopian</p> <p>11 tubes for daily users, it's 1.40. Statistically</p> <p>12 significant, correct?</p> <p>13 A. That's what they report.</p> <p>14 Q. Which is very close to the overall</p> <p>15 pooled estimate of 1.40 -- I mean 1.47, correct?</p> <p>16 MS. CURRY: Object to the form.</p> <p>17 THE WITNESS: Those numbers are</p> <p>18 close. But as we've discussed before, I</p> <p>19 think it's artifactual to look at women</p> <p>20 with patent fallopian tubes.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. Mrs. Converse would -- based on the</p> <p>23 data from Nurses' Health Study 1, looking at just</p> <p>24 all women, would have an increased risk of 27</p>
<p style="text-align: right;">Page 235</p> <p>1 MS. CURRY: So we need to switch</p> <p>2 the sticker.</p> <p>3 MS. BROWN: Yeah, you can switch</p> <p>4 it.</p> <p>5 MS. O'DELL: Yeah, let's just</p> <p>6 switch that out, shall we?</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. So, Dr. Saenz, do you have table --</p> <p>9 supplemental Table 1?</p> <p>10 THE WITNESS: That's figure.</p> <p>11 She said table.</p> <p>12 No, I have supplemental</p> <p>13 figure -- oh, table. Sorry. Here we</p> <p>14 go.</p> <p>15 Do you want to put that on</p> <p>16 there?</p> <p>17 MS. O'DELL: All right. Are we</p> <p>18 together?</p> <p>19 MS. BROWN: Yes.</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. Supplemental Table 1 is data from</p> <p>22 the Nurses' Health Study, correct?</p> <p>23 A. Yes.</p> <p>24 Q. Have you seen this before?</p>	<p style="text-align: right;">Page 237</p> <p>1 percent. True?</p> <p>2 MS. CURRY: Object to the form.</p> <p>3 THE WITNESS: The hazard ratio</p> <p>4 here was 1.27, that's correct.</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. And for women with patent fallopian</p> <p>7 tubes, which would include Ms. Converse, daily</p> <p>8 users had a 40 percent increased risk, which was</p> <p>9 statistically significant, correct?</p> <p>10 A. Again, that's not -- it's an</p> <p>11 artifactual manipulation of the data set that is</p> <p>12 not relevant to exposure.</p> <p>13 Q. That's -- I understand that's your</p> <p>14 view, ma'am, but that's what the data says,</p> <p>15 correct?</p> <p>16 MS. CURRY: Object to the form.</p> <p>17 THE WITNESS: That's what the</p> <p>18 reported hazard ratio is.</p> <p>19 MS. O'DELL: Okay. Let's turn</p> <p>20 now to the O'Brien "Douching and Genital</p> <p>21 Talc Use: Patterns of Use and</p> <p>22 Reliability of Self-Reported Exposure."</p> <p>23 And I would like to mark that as</p> <p>24 our next exhibit, which is Exhibit 27.</p>



<p style="text-align: right;">Page 238</p> <p>1 (Exhibit No. 27 was marked for 2 identification.) 3 BY MS. O'DELL: 4 Q. Do you have it in front of you, 5 ma'am? 6 A. Yes. Thank you. 7 Q. And this publication is a report of 8 the updated usage in the Sister Study based on a 9 follow-up questionnaire that was sent from 2017 10 to 2019. True? 11 A. Correct. 12 Q. And they looked at the -- they 13 compared the report of the women initially at 14 enrollment from 2003 to 2009, and the data that 15 was provided on the talc use and douching, and 16 they compared it to the data they obtained in 17 2017 to 2019. True? 18 A. Correct. 19 Q. And if you look at the results 20 in the abstract, and you go down midway, it says 21 87 percent providing the same responses about 22 genital talc use. 23 Do you see that? 24 A. Yes.</p>	<p style="text-align: right;">Page 240</p> <p>1 intervening years, before they were 2 queried again about talc use in 2017 to 3 2019, that was the only group that 4 actually increased their reports of use. 5 The other groups actually, if anything, 6 reported less use. But the ovarian 7 cancer patients themselves reported more 8 use, which is why the authors talk about 9 the potential for that recall bias. 10 BY MS. O'DELL: 11 Q. So turn to page 379 of the study, 12 ma'am. 379, right-hand side. 13 Do you see recall bias talc use was 14 slightly less consistent with 87 percent of women 15 providing the same response at follow-up as they 16 did enrollment, and specificity was 94 percent, 17 and it goes on to list some others. 18 And it says here: "The largest 19 source of inconsistency was 3,049 women, 20 10 percent of the sample, who initially reported 21 using genital talc in the 12 months before 22 enrollment but later responded that they did not 23 use it during that period." 24 So in fact, the difference, that</p>
<p style="text-align: right;">Page 239</p> <p>1 Q. And the authors go on to say that: 2 "Reliability did not vary by cancer status, race 3 and ethnicity, attained education or age, though 4 there was some evidence of recall bias for 5 genital talc use among ovarian cancer survivors." 6 Did I read that correctly? 7 A. Yes. 8 Q. And they also say, if you go down 9 in Conclusions: "Classification of ever use of 10 feminine hygiene products may be recalled with 11 good consistency." 12 Do you see that? 13 A. Yes. 14 Q. And it was the conclusion of the 15 authors that the data provided in the first round 16 at enrollment and from 2017 to 2019 that there 17 was -- good consistency really confirmed the 18 reliability of exposure information provided by 19 study participants. True? 20 MS. CURRY: Object to the form. 21 THE WITNESS: As a whole group, 22 but when they did essentially a subset 23 analysis looking at women that had been 24 diagnosed with ovarian cancer in the</p>	<p style="text-align: right;">Page 241</p> <p>1 was because more people said they used talc was 2 more people said they didn't use talc, correct? 3 A. That's correct, but that's not what 4 I said. What I said is that the only group that 5 reported using more talc was the women that were 6 diagnosed with ovarian cancer in the intervening 7 years. And that's actually on page 383. 8 Q. But you're not disagreeing with 9 what I just read to you as being incorrect, are 10 you? 11 A. I'm not disagreeing with that, but 12 I think what's relevant here is that it's the 13 cases, the women that had ovarian cancer in the 14 intervening years that increased their reported 15 use. That's an example of recall bias. 16 Q. You can put that aside. 17 I want to look at one other -- 18 actually two others, but let me just -- is there 19 any evidence that genital use of talc increases 20 the risk of uterine cancer? 21 A. No, I do not believe that there is. 22 Q. Is there any evidence that genital 23 use of talc increases the risk of cervical 24 cancer?</p>

<p style="text-align: right;">Page 242</p> <p>1 A. No, I do not believe there is.</p> <p>2 Q. Is there any evidence that the</p> <p>3 genital use of talc increases the risk of vaginal</p> <p>4 cancer?</p> <p>5 A. No, I do not believe there is.</p> <p>6 Q. Vulvar cancer?</p> <p>7 A. No, I do not believe there is.</p> <p>8 Q. Breast cancer?</p> <p>9 A. No. In fact, I think there's some</p> <p>10 literature that would say that breast cancer is</p> <p>11 not associated with the use of talc.</p> <p>12 Q. And that would be true essentially</p> <p>13 of uterine cancer, true, as well?</p> <p>14 A. I have reviewed, I want to say, I</p> <p>15 think five, but please don't hold me accountable</p> <p>16 because I don't have it here -- I think I've</p> <p>17 reviewed five studies on the risk of uterine</p> <p>18 cancer and the genital application of talc, and</p> <p>19 there's only one study that showed a positive</p> <p>20 association, and I think that may have been out</p> <p>21 of Australia, but when that data or that study</p> <p>22 was replicated, the positive finding did not hold</p> <p>23 up.</p> <p>24 Q. And in fact, in the recent study by</p>	<p style="text-align: right;">Page 244</p> <p>1 it open, because I just see your picture. But</p> <p>2 you have it on the screen there and you're able</p> <p>3 to see it?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Do you need me to share my</p> <p>6 screen at all, or are you good with what you're</p> <p>7 looking at?</p> <p>8 A. I think I'm good.</p> <p>9 Q. Okay. This study was a study that</p> <p>10 looked at data from the Sister's cohort study,</p> <p>11 correct?</p> <p>12 A. Yes. That's the study population,</p> <p>13 yes.</p> <p>14 Q. And these authors considered data</p> <p>15 from the Sister Study based on the fourth</p> <p>16 questionnaire that was obtained from 2017 to</p> <p>17 2019. True?</p> <p>18 A. I don't know that it was a fourth</p> <p>19 questionnaire. I don't have any data for that.</p> <p>20 But I do believe that the follow-up data that's</p> <p>21 presented in the study is from the query that was</p> <p>22 made between 2017 and 2019.</p> <p>23 Q. That's fair. If you'll turn to</p> <p>24 page 3, on the left-hand side under the figure,</p>
<p style="text-align: right;">Page 243</p> <p>1 O'Brien in May of 2024, which I'll mark as</p> <p>2 Exhibit 28, there was no association seen between</p> <p>3 genital talc use and uterine cancer, correct?</p> <p>4 A. In that study as well as in the</p> <p>5 Chang study that was also published in 2024. I</p> <p>6 believe that study also looked at what are</p> <p>7 classified as hormone sensitive cancers.</p> <p>8 (Exhibit No. 28 was marked for</p> <p>9 identification.)</p> <p>10 BY MS. O'DELL:</p> <p>11 Q. You should have O'Brien 2024 in the</p> <p>12 chat.</p> <p>13 MS. BROWN: It's in the chat.</p> <p>14 BY MS. O'DELL:</p> <p>15 Q. And if you will, please open that.</p> <p>16 MS. CURRY: So, Leigh, what you</p> <p>17 wanted to mark as 28 was O'Brien 2024</p> <p>18 that's in the chat?</p> <p>19 MS. O'DELL: That's correct.</p> <p>20 MS. CURRY: Okay.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. Do you have it, Doctor?</p> <p>23 A. Yes. I'm sorry, yes.</p> <p>24 Q. Okay. I can't tell when you have</p>	<p style="text-align: right;">Page 245</p> <p>1 do you see the paragraph beginning "More detailed</p> <p>2 information"?</p> <p>3 A. Yes.</p> <p>4 Q. It was obtained in the fourth</p> <p>5 follow-up questionnaire from 2017 to 2019. Do</p> <p>6 you see that?</p> <p>7 A. Fair enough.</p> <p>8 Q. And the difference in the fourth</p> <p>9 follow-up questionnaire as compared to the</p> <p>10 initial questions dealt with lifetime exposure,</p> <p>11 correct?</p> <p>12 MS. CURRY: Object to the form.</p> <p>13 THE WITNESS: I mean, they say:</p> <p>14 "We primarily focused on ever use versus</p> <p>15 never use for each product, but also</p> <p>16 examined frequency, duration and timing</p> <p>17 of use."</p> <p>18 So I don't see the word</p> <p>19 "lifetime."</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. Yes. In -- let me just compare it</p> <p>22 for you. In the Sister's enrollment they asked</p> <p>23 for usage in the 12 months prior to enrollment</p> <p>24 and from the ages 10 to 13, correct?</p>

<p style="text-align: right;">Page 246</p> <p>1 A. That's my recollection.</p> <p>2 Q. And in the follow-up questionnaire</p> <p>3 that we're talking about, they ask, How old were</p> <p>4 you when you first started using talc? They</p> <p>5 asked questions about the decades that you used</p> <p>6 talc. 20s and 30s, for example. True?</p> <p>7 A. Yes.</p> <p>8 Q. And in addition to asking how old</p> <p>9 you were when you first used talc, are you aware</p> <p>10 that they also asked how old you were when you</p> <p>11 last used talcum powder on or near your vaginal</p> <p>12 area. And are you aware of that?</p> <p>13 A. Yes.</p> <p>14 Q. And so that would allow the</p> <p>15 researchers to understand the range of use from</p> <p>16 beginning to end or the lifetime exposure. Is</p> <p>17 that fair?</p> <p>18 A. The range of use for those women,</p> <p>19 correct, or the duration, yes.</p> <p>20 Q. And so there could be women in the</p> <p>21 enrollment when asked the two finite questions,</p> <p>22 did I use it in the last 12 months or did I use</p> <p>23 from ages 10 to 13, they might say no, because</p> <p>24 they're 55 and they stopped at 45. And they</p>	<p style="text-align: right;">Page 248</p> <p>1 women were queried in 2017 to 2019. And</p> <p>2 so the questionnaires, you know, if you</p> <p>3 didn't have ovarian cancer by 2017 and</p> <p>4 you submitted your questionnaire, you --</p> <p>5 and you got it after, I'm not sure that</p> <p>6 this paper would have picked that up,</p> <p>7 right, because the queries were before</p> <p>8 that study came out.</p> <p>9 So I don't know that that's true</p> <p>10 because I don't know when the women --</p> <p>11 if you had turned your survey back in in</p> <p>12 2017, and you hadn't yet had ovarian</p> <p>13 cancer, you might not have reported it</p> <p>14 in this study, but maybe you were</p> <p>15 recorded in the O'Brien study.</p> <p>16 I don't know the answer to that.</p> <p>17 BY MS. O'DELL:</p> <p>18 Q. Are you sure about that?</p> <p>19 A. I'm not.</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 THE WITNESS: What I'm saying is</p> <p>22 I don't know where the queries and the</p> <p>23 case documentation overlap between these</p> <p>24 two studies. I don't know the answer to</p>
<p style="text-align: right;">Page 247</p> <p>1 started at age 20, so that's 25 years of use.</p> <p>2 But they would have said no in the</p> <p>3 initial study, and yet for the follow-up data,</p> <p>4 they would have reported that as having been</p> <p>5 exposed to talcum powder for basically decades.</p> <p>6 True?</p> <p>7 A. I think that's probably true.</p> <p>8 Q. And there were more women with</p> <p>9 ovarian cancer reported in -- in this study</p> <p>10 because of a longer period of follow-up than had</p> <p>11 been reported in prior studies. True?</p> <p>12 A. In prior publications of the Sister</p> <p>13 Study?</p> <p>14 Q. Correct.</p> <p>15 A. Well, not compared to Chang, but</p> <p>16 compared to the Gonzales study, yes.</p> <p>17 Q. And also compared to the O'Brien</p> <p>18 2020 study, there were more women --</p> <p>19 A. That's fair.</p> <p>20 Q. -- that had manifested ovarian</p> <p>21 cancer. True?</p> <p>22 MS. CURRY: Object to the form.</p> <p>23 THE WITNESS: I actually don't</p> <p>24 know that to be true, because these</p>	<p style="text-align: right;">Page 249</p> <p>1 that.</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. So this will help, I think, if you</p> <p>4 look at Figure 1.</p> <p>5 A. Okay.</p> <p>6 Q. Are you there?</p> <p>7 A. Yes, ma'am.</p> <p>8 Q. And if you look at -- there's a</p> <p>9 blue box at the bottom of the figure.</p> <p>10 A. Yes.</p> <p>11 Q. "Cancers diagnosed after</p> <p>12 follow-up." DFU4, which was after the</p> <p>13 information was obtained about usage, the</p> <p>14 follow-up questionnaire.</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And in fact, there were 30</p> <p>18 additional cases. True?</p> <p>19 A. Right. But I don't know that those</p> <p>20 weren't also collected for O'Brien 2020, and</p> <p>21 that's what you asked me before was did --</p> <p>22 Q. Well, they were after -- excuse me,</p> <p>23 they were after -- as I understand it, they were</p> <p>24 after 2019 and before September 2021.</p>

<p style="text-align: right;">Page 250</p> <p>1 A. Not for all of those women because</p> <p>2 some of them turned in their questionnaires in</p> <p>3 like 2017.</p> <p>4 Q. But these were women after the</p> <p>5 fourth questionnaire. The 30 were after that.</p> <p>6 They were not before the fourth -- the fourth</p> <p>7 questionnaire was completed.</p> <p>8 So I'm saying that --</p> <p>9 A. What? No.</p> <p>10 Q. Yeah, I'm --</p> <p>11 A. I don't -- I don't think that's</p> <p>12 actually -- if you -- so these cancers were</p> <p>13 diagnosed after this questionnaire was completed.</p> <p>14 But if you completed this questionnaire in 2017,</p> <p>15 how do we know that cancer wasn't picked up by</p> <p>16 the O'Brien 2020 study?</p> <p>17 Q. Let me just -- I don't believe</p> <p>18 that's the case, but I don't think -- let's don't</p> <p>19 get hung up on that.</p> <p>20 A. Okay. Fair enough.</p> <p>21 Q. There's something that I think we</p> <p>22 can agree on, that this is the maximum number of</p> <p>23 ovarian cancer patients that have ever been</p> <p>24 reported on from the Sister Study. True?</p>	<p style="text-align: right;">Page 252</p> <p>1 scenarios 2 and 3 demonstrate the range of</p> <p>2 results" --</p> <p>3 A. I'm sorry -- I'm sorry -- Leigh,</p> <p>4 I'm sorry. Hold on one second. The right-hand</p> <p>5 side on the top?</p> <p>6 Q. Yes. So page 4, right-hand side,</p> <p>7 top of the page. Top of the page --</p> <p>8 A. Oh, okay. Sorry, the last sentence</p> <p>9 of that paragraph. Yes.</p> <p>10 Q. "We did this for each of 10 copies"</p> <p>11 --</p> <p>12 A. I'm with you. I'm with you. Okay.</p> <p>13 Q. All right. And then at the bottom</p> <p>14 of that paragraph, they say: "Together,</p> <p>15 scenarios 2 and 3 demonstrate the range of</p> <p>16 results defined by how women in the undefined</p> <p>17 category are classified with the true exposure</p> <p>18 distribution falling somewhere between the two</p> <p>19 extremes."</p> <p>20 Did I read that correctly?</p> <p>21 A. You read that correctly.</p> <p>22 Q. And they also, looking at the</p> <p>23 bottom of that column, addressed the potential</p> <p>24 for recall bias. Correct?</p>
<p style="text-align: right;">Page 251</p> <p>1 A. True.</p> <p>2 Q. And the authors conducted a</p> <p>3 statistical analysis to evaluate the use of</p> <p>4 genital talc across the entire population of</p> <p>5 women in the study. True?</p> <p>6 A. I mean this paper is a statistical</p> <p>7 analysis, that's correct.</p> <p>8 Q. That's right.</p> <p>9 And if you'll turn to page 4, they</p> <p>10 conducted quantitative bias analyses. Do you see</p> <p>11 that?</p> <p>12 A. Yes.</p> <p>13 Q. Where they first looked at a</p> <p>14 scenario where there was no correction of data.</p> <p>15 The second scenario was contradictory data was</p> <p>16 corrected. The third scenario was contradictory</p> <p>17 data correction plus categorizing missing or</p> <p>18 undefined as exposed. And fourth, the scenario</p> <p>19 was contradictory data correction with multiple</p> <p>20 amputation of missing or undefined data.</p> <p>21 Did I read that correctly?</p> <p>22 A. Yes.</p> <p>23 Q. And the authors go on to say on the</p> <p>24 right-hand side at the top: "Together,</p>	<p style="text-align: right;">Page 253</p> <p>1 A. That's what they said they did.</p> <p>2 Q. It says: "We also generated a</p> <p>3 single recall bias corrected estimate that</p> <p>4 simultaneously corrected cases and non-cases. We</p> <p>5 assumed 25 percent of ovarian cancer initially</p> <p>6 categorizes infrequent and short-term users were</p> <p>7 reassigned to non-users." Right?</p> <p>8 A. To be non-users, yes.</p> <p>9 Q. And they reported short-term use or</p> <p>10 infrequent use, they made those people non-users,</p> <p>11 correct?</p> <p>12 A. In 10 percent of the women without</p> <p>13 ovarian cancer initially categorized as never</p> <p>14 users were reassigned to infrequent short-term</p> <p>15 users.</p> <p>16 Q. Yes. And that was the assumption</p> <p>17 that they make. They said: "HRs based on this</p> <p>18 correction are included in the results as</p> <p>19 examples of possible yet cautious estimates of</p> <p>20 the association between genital talc use and</p> <p>21 ovarian cancer after correcting for case</p> <p>22 differential recall."</p> <p>23 Did I read that correctly?</p> <p>24 A. Yes, you read that correctly.</p>

<p style="text-align: right;">Page 254</p> <p>1 Q. And you're critical of their 2 methodology. 3 MS. CURRY: Object to the form. 4 THE WITNESS: I am -- 5 BY MS. O'DELL: 6 Q. True? 7 A. I am critical of this paper for 8 several different reasons. 9 Q. Okay. I want to hear them, but I 10 want to set the table a little bit more first, 11 okay? 12 If you'll turn over to page 7 of 13 this study, Table 2, this is a report of the four 14 scenarios we talked about a few minutes ago. 15 Correct? 16 A. Yes. 17 Q. And if you'll look at -- there's 18 scenario 2 and 3. And we just read that the 19 authors feel that the true exposure distribution 20 is between scenario 2 and scenario 3. 21 Do you recall reading that? 22 A. Yes. 23 Q. And scenario 2 shows an increased 24 risk for ever use of talc with ovarian cancer of</p>	<p style="text-align: right;">Page 256</p> <p>1 A. One of these outcomes is assuming 2 that the unexposed patients are actually 3 unexposed. The other is assuming they're exposed 4 if they reported unexposed at enrollment and they 5 were missing data at follow-up. 6 And what the authors actually say 7 is that that category is actually overrepresented 8 by patients that were diagnosed with ovarian 9 cancer. And that's back to where you and I were 10 before -- 11 Q. I want to see where you say that. 12 You say the authors state that? 13 A. Yes, ma'am. 14 Q. And I would like to understand what 15 you're talking about. 16 A. Okay. So I am on page 3, left-hand 17 column, and the authors -- it's the very last two 18 sentences of the left-hand column. 19 "We also used quantitative bias 20 analyses to implement different approaches for 21 imputing exposure in women who initially reported 22 never use but did not complete the follow-up 23 questionnaire. These comparisons were crucial 24 for understanding potential biases as women with</p>
<p style="text-align: right;">Page 255</p> <p>1 1.17. 2 Do you see that at the bottom? 3 A. No. I don't know what -- 4 Q. Scenario 2 at the bottom. 5 A. Oh, okay. So -- got it. Okay. 6 Yep, I'm with you. 7 Q. Scenario 2 is 1.17, and scenario 3 8 is 3.34. Do you see that? 9 A. Yes. 10 Q. And the authors have stated that 11 they believe the true exposure distribution and 12 ostensibly the increased risk is between those 13 two data points. Do you see that? 14 MS. CURRY: Object to the form. 15 THE WITNESS: So they're 16 proposing hypothetically that this is 17 where they believe the true exposure 18 data is. One of these outcomes is a 19 nonstatistically significant finding, 20 and the other is a statistically 21 significant increased risk. One of 22 these -- 23 BY MS. O'DELL: 24 Q. Yeah, so --</p>	<p style="text-align: right;">Page 257</p> <p>1 incident cancer were overrepresented in this 2 undefined group." 3 Q. And so you read that correctly. 4 But they're not referring there specifically to 5 scenario 2 and 3, but they have said that women 6 with incident cancer were unrepresented in this 7 undefined group. I agree with you. 8 A. But that -- 9 MS. CURRY: Object to the form. 10 THE WITNESS: But that is 11 scenario 3. That is scenario 3. 12 BY MS. O'DELL: 13 Q. So you view that to be scenario 3? 14 MS. CURRY: Object to the form. 15 THE WITNESS: Yes. 16 BY MS. O'DELL: 17 Q. They go on to report in Table 3 -- 18 A. Let me get back there. Sorry. 19 Q. Table 3. 20 A. Not there yet. Okay, I'm there. 21 Q. Page 10. They -- if you look at 22 the ovarian cancer column with recall bias 23 correction. 24 Do you see that?</p>



<p style="text-align: right;">Page 258</p> <p>1 A. Yes.</p> <p>2 Q. And so this is their estimate, and</p> <p>3 they're saying we assume there's some recall</p> <p>4 bias, and we're going to correct for that. In</p> <p>5 other words, we're going to reduce the risk</p> <p>6 adjusted to account for recall bias. True?</p> <p>7 A. That's what they say. What I don't</p> <p>8 understand is how do you decide what that</p> <p>9 percentage should be.</p> <p>10 Q. And their analysis for ever versus</p> <p>11 never use of genital talc, they reported a hazard</p> <p>12 ratio of 1.40, and it was statistically</p> <p>13 significant, correct?</p> <p>14 A. That number was there, but that's</p> <p>15 drawn from them using a certain percentage of</p> <p>16 patients that they say were at risk for recall</p> <p>17 bias, and the designation of what that percentage</p> <p>18 should be is arbitrary.</p> <p>19 Q. Okay. And -- and you view it as</p> <p>20 arbitrary, but that's what the data shows on this</p> <p>21 table, ever versus never is 1.40, if I stated the</p> <p>22 data correctly.</p> <p>23 A. With the correction of --</p> <p>24 Q. Yes or no?</p>	<p style="text-align: right;">Page 260</p> <p>1 what I'm referring to. What they did in this</p> <p>2 statistical analysis was they looked at</p> <p>3 reclassification at various percentages, and when</p> <p>4 they reclassified 25 percent of the patients,</p> <p>5 their results were statistically significant, but</p> <p>6 when they reclassified 50 percent of the</p> <p>7 patients, they weren't.</p> <p>8 And so what I'm saying is arbitrary</p> <p>9 is how do you decide that that's the percentage</p> <p>10 that you should correct for? That in itself is</p> <p>11 arbitrary.</p> <p>12 Q. Would you agree with me that -- and</p> <p>13 you said this before -- most women begin to use</p> <p>14 talc in their 20s, they used during their 20s and</p> <p>15 30s, and they used it consistently or frequently.</p> <p>16 You agree with that, right?</p> <p>17 A. What --</p> <p>18 Q. Based on the data that's in Cramer</p> <p>19 and many other studies, true?</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 THE WITNESS: What I said before</p> <p>22 is that most women that use talc start</p> <p>23 in either their teens or 20s, and the</p> <p>24 average duration is about 20 years.</p>
<p style="text-align: right;">Page 259</p> <p>1 A. With the correction of 25 percent.</p> <p>2 That's not what the data is if you used a</p> <p>3 different number for the correction.</p> <p>4 Q. Well, it was 25 percent of women --</p> <p>5 25 percent of women they're putting into</p> <p>6 non-users that would -- that would decrease the</p> <p>7 hazard ratio toward the null, correct?</p> <p>8 A. That's not the -- no, this is the</p> <p>9 correction of the recall bias, and when you look</p> <p>10 at --</p> <p>11 Q. I understand.</p> <p>12 A. When you look at the -- I'm trying</p> <p>13 to find the table that I had before.</p> <p>14 Q. I want you -- so --</p> <p>15 A. Go ahead. I'm sorry. Yes, ma'am.</p> <p>16 Q. So just focus on this aspect,</p> <p>17 because this is -- you know, if they took 25</p> <p>18 percent of the women and put them out of -- took</p> <p>19 them out of the group of users into -- and put</p> <p>20 them into the group of non-users, that would</p> <p>21 decrease the hazard ratio toward the null,</p> <p>22 correct?</p> <p>23 A. That's not what the correction --</p> <p>24 when I'm referring to the 25 percent, that's not</p>	<p style="text-align: right;">Page 261</p> <p>1 That is what I have said before, and</p> <p>2 that is based on Cramer and Wu.</p> <p>3 BY MS. O'DELL:</p> <p>4 Q. And isn't it also true that women</p> <p>5 who use talc and begin in that time period, they</p> <p>6 used talc habitually?</p> <p>7 MS. CURRY: Object to the form.</p> <p>8 THE WITNESS: I don't -- I mean,</p> <p>9 I don't know what the word "habitual"</p> <p>10 really means. What I'm saying is that I</p> <p>11 think they do have a duration of about</p> <p>12 20 years.</p> <p>13 BY MS. O'DELL:</p> <p>14 Q. And it's your opinion that more</p> <p>15 than 25 percent of women who said that they were</p> <p>16 a talc user, because we're talking about ever</p> <p>17 versus never talc user, would have misrepresented</p> <p>18 that data in a study questionnaire. Is that your</p> <p>19 testimony --</p> <p>20 MS. CURRY: Object to the form.</p> <p>21 BY MS. O'DELL:</p> <p>22 Q. -- more than 25 percent would have</p> <p>23 done it?</p> <p>24 A. I don't know. Because these</p>

<p style="text-align: right;">Page 262</p> <p>1 calculations are arbitrary, so I don't actually 2 have any data on that. 3 What I do know -- the only thing 4 that I do know from Dr. O'Brien's prior 5 publication is that the women that are more 6 likely to say that they now use more talc or are 7 talc users are women that have been diagnosed 8 with ovarian cancer. That is the only population 9 out of her study in 2023 that increased their -- 10 that had an increase in stating that they had 11 used talc when they had not before. 12 Q. Okay. I think that misrepresents 13 what is being done here. 14 But if you'll turn to Table A1, 15 Dr. Saenz. Supplemental Table A1. 16 A. Okay, I'm there. 17 Q. And you look at women, and just 18 take it from the top, cases who ever used genital 19 talc reassigned to non-users. Do you see that? 20 It's the first group of data. 21 A. Oh, yes. I'm sorry, yes. 22 Q. Table A1. 23 A. Yes. Go right ahead. 24 Q. Zero reassigned -- zero percent</p>	<p style="text-align: right;">Page 264</p> <p>1 null, that was accurate, true? 2 MS. CURRY: Object to the form. 3 THE WITNESS: Assigning users to 4 non-users? 5 BY MS. O'DELL: 6 Q. Yes. 7 A. Yes. But again, it's a statistical 8 manipulation. It's not the actual data. So I 9 don't -- I don't know what that means. It could 10 just as easily look at some of the other 11 reassignments that are not statistically 12 significant. 13 Q. Okay. So -- but the zero percent 14 reassignment is 1.82, and that's statistically 15 significant, correct? 16 A. Correct. But what's most 17 interesting to me here is that that data is not 18 substantiated by Chang's publication on the exact 19 same women. The only difference being that these 20 women were requeried in 2017 to 2019 about their 21 talc use. 22 And so Chang looked at different 23 categories of hygiene products, et cetera, et 24 cetera, and talc was in that group. And even so</p>
<p style="text-align: right;">Page 263</p> <p>1 reassigned. Do you see that? 2 A. Yes. 3 Q. There's been no adjustment 4 whatsoever. 5 A. Correct. 6 Q. Zero reassigned. What is the odds 7 ratio for that group of women? 8 A. Well, it's a hazard ratio, and 9 it's -- 10 Q. Fair enough. 11 A. -- 1.82. 12 Q. And it's statistically significant, 13 correct? 14 A. The confidence interval, yes, it's 15 statistically significant. 16 Q. And if you look at the bottom of 17 the table when there's been a reassignment of 18 infrequent short-term users with ovarian cancer 19 to non-users, and 10 percent of non-case, 20 non-users to be short-term infrequent users is 21 1.40, correct? 22 A. Correct. 23 Q. And so when I said it was -- that 24 adjustment would bias it or reduce it towards the</p>	<p style="text-align: right;">Page 265</p> <p>1 looking at the Sister Study, Chang did not find 2 an increased risk in these same women for use of 3 the perineal application of talc and the 4 development of ovarian cancer, and that study was 5 published in 2024 as well. 6 Q. Well, actually, in fact, what Chang 7 found was a 1.04 increased risk for one 8 frequency. 9 A. No, Chang -- 10 MS. CURRY: Object to the form. 11 THE WITNESS: When Chang pulled 12 out talc from the hygiene product 13 collective, the talc data was not 14 statistically significant. The hygiene 15 data had a statistical significance, and 16 that was contributed to by use of 17 douching products, but the actual talc 18 was not statistically significant. 19 BY MS. O'DELL: 20 Q. Let's go back to Table 3, and look 21 at the column for recall bias correction. 22 Do you see that? 23 A. Where -- am I missing this? 24 Q. Table 3, ma'am.</p>

<p style="text-align: right;">Page 266</p> <p>1 A. I don't see recall bias correction.</p> <p>2 Do you? Oh, for ovarian cancer. I'm sorry.</p> <p>3 Okay, yes.</p> <p>4 Q. You're not running the clock on me,</p> <p>5 are you, Dr. Saenz?</p> <p>6 A. Ma'am, come on now, you know me.</p> <p>7 Q. I'm teasing. I'm teasing.</p> <p>8 A. I don't play games.</p> <p>9 Q. All right.</p> <p>10 A. I'm with you. I'm with you.</p> <p>11 Q. Long-term use showed --</p> <p>12 demonstrated a hazard ratio of 2.01, correct?</p> <p>13 Statistically significant.</p> <p>14 A. Long-term use greater than two</p> <p>15 decades --</p> <p>16 MS. CURRY: This is douching.</p> <p>17 THE WITNESS: Oh, down here.</p> <p>18 Yes, ma'am, 2.01.</p> <p>19 BY MS. O'DELL:</p> <p>20 Q. For ever versus never use in the</p> <p>21 20s, it was 1.88 statistically significant,</p> <p>22 correct?</p> <p>23 A. Ever versus never use in the 20s,</p> <p>24 yes, that is correct.</p>	<p style="text-align: right;">Page 268</p> <p>1 Q. Yeah, but that's what their</p> <p>2 conclusion was.</p> <p>3 A. That's their conclusion, yes.</p> <p>4 MS. O'DELL: Okay. Let's go off</p> <p>5 the record just for a moment, please.</p> <p>6 THE WITNESS: Yes, ma'am.</p> <p>7 (Recess.)</p> <p>8 BY MS. O'DELL:</p> <p>9 Q. So, Dr. Saenz, I want to move</p> <p>10 forward in your report several pages, out of</p> <p>11 epidemiology into a section that you entitled</p> <p>12 "Inflammation as the mechanism by which talc</p> <p>13 induces ovarian cancer."</p> <p>14 And specifically, I want to -- oh,</p> <p>15 forgive me, there's another title. Sorry. 49 is</p> <p>16 where I wanted to go, "Lack of data that talc</p> <p>17 induces carcinogenesis in ovarian epithelial</p> <p>18 cells."</p> <p>19 Let me know when you turn there.</p> <p>20 A. I'm there.</p> <p>21 Q. And you have a discussion of -- of</p> <p>22 the in vitro studies that have been done on talc.</p> <p>23 You mentioned studies like the Shukla study,</p> <p>24 Buz'Zard. You also mention Emi, and then the</p>
<p style="text-align: right;">Page 267</p> <p>1 Q. And then -- and then 2.08 was the</p> <p>2 ever versus never hazard ratio for use in the</p> <p>3 30s, correct?</p> <p>4 A. Correct. And all of these were</p> <p>5 recall bias corrections, so the manipulated</p> <p>6 dataset.</p> <p>7 MS. O'DELL: Move to strike</p> <p>8 "manipulated."</p> <p>9 BY MS. O'DELL:</p> <p>10 Q. Let me ask you to turn to page 13.</p> <p>11 A. 13?</p> <p>12 Q. Correct.</p> <p>13 A. I'm there.</p> <p>14 Q. Look at the right side of the page,</p> <p>15 midway down, it says "Our findings." Do you see</p> <p>16 that?</p> <p>17 A. Yes, ma'am.</p> <p>18 Q. The authors concluded that the</p> <p>19 positive association between genital talc use and</p> <p>20 ovarian cancer in this study was consistent with</p> <p>21 previous studies. True?</p> <p>22 A. You're not asking me if you read it</p> <p>23 correctly, right? Because you editorialized</p> <p>24 there, but --</p>	<p style="text-align: right;">Page 269</p> <p>1 work of Dr. Saed.</p> <p>2 And I want to ask first is to have</p> <p>3 you look at page 49, and the first sentence in</p> <p>4 this section where you say: "Plaintiff's experts</p> <p>5 in this litigation have offered the opinion that</p> <p>6 there is in vitro data and in vivo animal data</p> <p>7 that talc can induce malignant transformation in</p> <p>8 normal ovarian epithelial."</p> <p>9 And you say: "This is pure</p> <p>10 speculation. Often cited are in vitro studies</p> <p>11 that report that talc can alter cell viability,</p> <p>12 proliferation and gene expression, but none of</p> <p>13 these endpoints are actual" -- excuse me -- "are</p> <p>14 an actual demonstration of malignant</p> <p>15 transformation and can in fact be manifestations</p> <p>16 of normal cellular responses to any change in the</p> <p>17 environment."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 Q. And this whole section in your</p> <p>21 report is new. Correct?</p> <p>22 MS. CURRY: Object to the form.</p> <p>23 THE WITNESS: I believe that I</p> <p>24 had some discussion regarding Dr. Saed</p>

<p style="text-align: right;">Page 270</p> <p>1 before, but I think that may be</p> <p>2 augmented. I don't know where the pink</p> <p>3 copy is, but I think I had some</p> <p>4 discussion of Dr. Saed before.</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. Is it your view that in order for a</p> <p>7 study to demonstrate that talc induces</p> <p>8 carcinogenesis that there must be malignant</p> <p>9 transformation?</p> <p>10 A. Yes.</p> <p>11 Q. Is there any demonstration that</p> <p>12 talc causes reactive oxygen species, gene</p> <p>13 expression, cell proliferation, or anything else</p> <p>14 that would persuade you that talc can induce</p> <p>15 inflammation?</p> <p>16 MS. CURRY: Object to the form.</p> <p>17 THE WITNESS: So if what we see</p> <p>18 is limited to those things that you just</p> <p>19 characterized, then because those can</p> <p>20 also be normal cellular functions, I do</p> <p>21 not believe that an experiment can claim</p> <p>22 that with the production of reactive</p> <p>23 oxygen species, changes in gene</p> <p>24 expression or increased proliferation,</p>	<p style="text-align: right;">Page 272</p> <p>1 BY MS. O'DELL:</p> <p>2 Q. And is it your understanding that</p> <p>3 the plaintiff's experts are arguing that Shukla,</p> <p>4 Buz'Zard, and Emi are demonstrating malignant</p> <p>5 transformation? Do you understand that to be</p> <p>6 their conclusion?</p> <p>7 MS. CURRY: Object to the form.</p> <p>8 THE WITNESS: So originally</p> <p>9 Dr. Clarke-Pearson actually did say that</p> <p>10 about the Emi paper, but then in</p> <p>11 deposition he retracted that statement</p> <p>12 when he looked at the paper and saw that</p> <p>13 it was a paper on macrophages and that</p> <p>14 it was reflective of alterations in the</p> <p>15 immune environment.</p> <p>16 BY MS. O'DELL:</p> <p>17 Q. And is it your -- before I go on,</p> <p>18 is it your evaluation and analysis that Dr. Wolf</p> <p>19 in her report is opining that all in vitro</p> <p>20 studies demonstrate malignant transformation?</p> <p>21 MS. CURRY: Object to the form.</p> <p>22 THE WITNESS: No, and I don't</p> <p>23 think I said that she said that all in</p> <p>24 vitro studies demonstrate malignant</p>
<p style="text-align: right;">Page 271</p> <p>1 that that equates to malignant</p> <p>2 transformation. Those are things that</p> <p>3 can be associated with a cancer</p> <p>4 phenotype, but they can also be</p> <p>5 associated with normal cellular</p> <p>6 function.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. And you understand that plaintiff's</p> <p>9 experts are not arguing that some of those things</p> <p>10 can also be associated with normal cell function.</p> <p>11 You -- you understand that, correct?</p> <p>12 MS. CURRY: Object to the form.</p> <p>13 THE WITNESS: What I have seen</p> <p>14 in their reports is that they have said</p> <p>15 that seeing those things means that</p> <p>16 malignant transformation has happened.</p> <p>17 So -- I mean, we're sort of doing a</p> <p>18 double negative. By extraction, I'm not</p> <p>19 saying that they're not saying that</p> <p>20 those things can't be normal cellular</p> <p>21 function, but they're saying basically</p> <p>22 that those are hallmarks of malignant</p> <p>23 transformation, and I'm saying it's not</p> <p>24 mutually exclusive.</p>	<p style="text-align: right;">Page 273</p> <p>1 transformation.</p> <p>2 BY MS. O'DELL:</p> <p>3 Q. I think you may have misspoke a few</p> <p>4 minutes ago, and I just want to make sure that we</p> <p>5 had an understanding.</p> <p>6 So let me ask you about your review</p> <p>7 of the in vitro studies regarding talc. In your</p> <p>8 discussion, did you endeavor to analyze all</p> <p>9 published in vitro studies that evaluated talc?</p> <p>10 A. I don't know that I've looked at</p> <p>11 all in vitro studies that involve talc, but I</p> <p>12 believe that I've looked at multiple studies that</p> <p>13 involve talc and the risk of developing ovarian</p> <p>14 cancer or the purported risk of inducing</p> <p>15 malignant transformation.</p> <p>16 Q. You note the Emi study --</p> <p>17 MS. O'DELL: And I want to mark</p> <p>18 that quickly, and I guess that will be</p> <p>19 Exhibit 29.</p> <p>20 (Exhibit No. 29 was marked for</p> <p>21 identification.)</p> <p>22 BY MS. O'DELL:</p> <p>23 Q. The authors in Emi acknowledge that</p> <p>24 talc is not inert. Are you aware of that?</p>

<p style="text-align: right;">Page 274</p> <p>1 A. Can you direct me to where you are</p> <p>2 saying they state that? Oh, right there. So</p> <p>3 sorry.</p> <p>4 So they put "inert" in quotes. So</p> <p>5 in other words, they're characterizing they don't</p> <p>6 think they are inert.</p> <p>7 Q. They don't think that talc is</p> <p>8 inert --</p> <p>9 A. Correct.</p> <p>10 Q. -- is that what you're saying?</p> <p>11 A. Yes.</p> <p>12 Q. And Emi was published in</p> <p>13 Epigenetics, correct?</p> <p>14 A. Yes.</p> <p>15 Q. And with researchers from Brown</p> <p>16 University, correct?</p> <p>17 A. And some other places, I think,</p> <p>18 yeah.</p> <p>19 Q. That's fair. University of Puerto</p> <p>20 Rico, Brown University, and maybe Rhode Island</p> <p>21 Hospital.</p> <p>22 Do you have any criticism of the</p> <p>23 methodology that the researchers in Emi used?</p> <p>24 MS. CURRY: Object to the form.</p>	<p style="text-align: right;">Page 276</p> <p>1 analysis has identified that pathways affected by</p> <p>2 talc included cell proliferation, immune response</p> <p>3 in signaling, immunosurveillance, apoptosis.</p> <p>4 These results help explain our prior finding of</p> <p>5 reduced tumoricidal activity of J774 cells after</p> <p>6 talc exposure."</p> <p>7 I have -- the first question is --</p> <p>8 the first sentence in talking about cell</p> <p>9 proliferation, immune response in signaling and</p> <p>10 immunosurveillance and apoptosis, those are all</p> <p>11 part of the inflammation cascade, true?</p> <p>12 MS. CURRY: Object to the form.</p> <p>13 THE WITNESS: They certainly can</p> <p>14 be.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. And -- okay. There's many more</p> <p>17 questions I would like to ask you about that, but</p> <p>18 I do not have time.</p> <p>19 A. We're done with that one?</p> <p>20 Q. We are.</p> <p>21 A. Okay.</p> <p>22 Q. So moving right along. You did</p> <p>23 not -- there's a study about "The effect of talc</p> <p>24 particles on phagocytes in co-culture with</p>
<p style="text-align: right;">Page 275</p> <p>1 THE WITNESS: Well, so the</p> <p>2 only -- I mean, the -- the problem --</p> <p>3 one of the -- one of the problems that I</p> <p>4 have with the Emi study is that they</p> <p>5 used titanium dioxide beads as their</p> <p>6 control, and they found that the cells</p> <p>7 treated with their so-called control</p> <p>8 actually had the same changes in</p> <p>9 cellular metabolism and the changes they</p> <p>10 observed with the titanium dioxide as</p> <p>11 they did with the talc.</p> <p>12 So that's not really a good</p> <p>13 control because there were changes, and</p> <p>14 they were the same types of changes that</p> <p>15 the authors saw with the application of</p> <p>16 talc. So I think that's a problem that</p> <p>17 you don't -- that there wasn't actually</p> <p>18 a control that didn't induce those same</p> <p>19 effects.</p> <p>20 BY MS. O'DELL:</p> <p>21 Q. If you will turn to page 1068.</p> <p>22 Left-hand column at the top.</p> <p>23 A. Yes.</p> <p>24 Q. They actually state that: "Pathway</p>	<p style="text-align: right;">Page 277</p> <p>1 ovarian cells" by Mandarinino.</p> <p>2 You did not review that paper, did</p> <p>3 you?</p> <p>4 A. I did not.</p> <p>5 Q. I want to now turn your attention</p> <p>6 to page 54 of your report.</p> <p>7 MS. CURRY: I'm sorry. I just</p> <p>8 have an objection to the last question.</p> <p>9 Mandarinino 2020 is actually cited in</p> <p>10 her --</p> <p>11 THE WITNESS: Oh, so I guess I</p> <p>12 did. I didn't recall it.</p> <p>13 MS. O'DELL: Dawn, objection to</p> <p>14 form I think is proper.</p> <p>15 MS. CURRY: I was just trying to</p> <p>16 clarify for the record --</p> <p>17 THE WITNESS: I'm sorry. I</p> <p>18 guess I did. I mean, it wouldn't be on</p> <p>19 my list if I hadn't read it. So I</p> <p>20 apologize. I'm not trying to keep</p> <p>21 anything from you. I just forgot.</p> <p>22 BY MS. O'DELL:</p> <p>23 Q. You did not describe the Mandarinino</p> <p>24 paper in your report, did you?</p>



<p style="text-align: right;">Page 278</p> <p>1 A. No, but I believe that I read it 2 because I think Dr. Clarke-Pearson cited to it in 3 his report. And so sometimes when another expert 4 cites to a report, I'll go and look at it to see 5 if it's anything that I need to include. 6 Q. And what was your basis for not 7 including it? 8 A. I don't think it added anything to 9 the science. 10 Q. You don't. Okay. 11 Turning to page 54. Your 12 discussion of asbestos begins on page 54, and in 13 your discussion -- and I'll just turn you to page 14 56, you focus on the Slomovitz publication from 15 2021, correct? 16 A. You're in the middle of the page, 17 correct? 18 Q. Yes, I am. 19 A. Yes. I see that. 20 Q. And Dr. Slomovich's paper does not 21 include any new research, correct? 22 MS. CURRY: Object to the form. 23 THE WITNESS: It's a summary 24 paper, correct. It's a review.</p>	<p style="text-align: right;">Page 280</p> <p>1 Dr. Slomovitz, Monk, Haydu, Taub and Coleman? 2 A. I know several of them 3 professionally through -- 4 Q. That's what I'm asking. 5 A. -- yeah, through the SGO, mm-hmm. 6 And through -- 7 Q. How do you know them? 8 A. I know Dr. Slomovitz through the 9 SGO. I know Dr. Coleman because I believe he and 10 I both served on the board of directors for the 11 Foundation for Women's Cancer at the same time, 12 or at least we overlapped. 13 And I know Dr. Monk, I've had -- 14 gosh, it goes way back -- I think when I was 15 interviewing for fellowship, he was a fellow, and 16 then I've run into him at various meetings. 17 Q. Okay. Have you talked to him about 18 talc and ovarian cancer? 19 A. No. Not any of them. 20 Q. Does this Slomovitz review paper 21 state that talc is safe for use in the genital 22 area? Does it reach that conclusion? 23 MS. CURRY: Object to the form. 24 THE WITNESS: I don't believe</p>
<p style="text-align: right;">Page 279</p> <p>1 BY MS. O'DELL: 2 Q. It's a review? 3 A. That's correct. It's an analysis 4 and a review, yes. 5 Q. Well, it's a review paper, as you 6 pointed out, and as a criticism of other review 7 articles, it has no new primary data, correct? 8 A. That is correct. 9 Q. And focusing on Slomovitz -- and 10 just to make sure we're clear, it's your opinion 11 that it doesn't matter if there's asbestos in 12 Johnson's baby powder or Shower to Shower, your 13 opinion is that those products do not cause 14 ovarian cancer. Fair? 15 A. Fair. 16 Q. And since we talked last, you've 17 not seen any of the testing results or data about 18 the presence of asbestos in Johnson's baby powder 19 or Shower to Shower, true? 20 MS. CURRY: Object to the form. 21 THE WITNESS: Correct. 22 BY MS. O'DELL: 23 Q. And Dr. Slomovitz and others -- by 24 the way, do you know these other authors,</p>	<p style="text-align: right;">Page 281</p> <p>1 that they draw that conclusion. I 2 believe that they conclude that there's 3 a problem with misclassification of the 4 cases potentially, and that without 5 actual review of the pathologic data to 6 separate peritoneal mesothelioma from 7 ovarian cancer cases, those 8 classifications are potentially 9 confounded. 10 BY MS. O'DELL: 11 Q. And they actually say that the 12 cases may be misdiagnosed as from ovarian 13 cancer -- ovarian cancer cases may be 14 misdiagnosed, and they're really primarily 15 peritoneal or peritoneal mesothelioma -- 16 A. Uh -- 17 Q. Let me strike that and start again. 18 I misspoke. 19 A. Yeah. 20 Q. They say some ovarian cancers may 21 be misdiagnosed and they're really mesothelioma. 22 They also acknowledge that some mesothelioma 23 cases may be misdiagnosed and are really ovarian 24 cancers. True?</p>

<p style="text-align: right;">Page 282</p> <p>1 A. I think that based on when those 2 cases were analyzed that were reviewed, the ones 3 they're commenting on for IARC to make their 4 conclusions, since we didn't have the 5 immunohistochemistry techniques that we do now, 6 that's certainly a problem potentially. Also 7 because a lot of the classifications were done 8 off of death certificates and not actually 9 medical records, that's also a problem. 10 Q. So if you will turn to page 127, 11 Dr. Saenz, of the Slomovitz paper. 12 A. I don't have it. We didn't mark it 13 yet. 14 Q. I thought we marked it as exhibit 15 -- 16 A. No, ma'am. Paula is working on it. 17 MS. O'DELL: Sorry, Paula, if I 18 got ahead of you. Exhibit 29, I guess. 19 MS. BROWN: 30. 20 MS. O'DELL: 30. 21 (Exhibit No. 30 was marked for 22 identification.) 23 MS. CURRY: You have about two 24 minutes left on general, Leigh.</p>	<p style="text-align: right;">Page 284</p> <p>1 Q. Have you endeavored to identify all 2 of the recent publications regarding ovarian 3 cancer and exposure to asbestos and described 4 them in your report? 5 A. No, not in the same way that I did 6 for talc. Primarily because, again, if asbestos 7 was in the talc, then the baby powder literature 8 should reflect an increased risk of developing 9 ovarian cancer. And so what the actual 10 constituents are in the baby powder do not matter 11 to me because the baby powder literature doesn't 12 reflect the increased risk of developing ovarian 13 cancer with the perineal application of talc. 14 Q. Well, in fact, there is literature 15 that does reflect an increased risk, Dr. Saenz. 16 It's your opinion that it's not causal, correct? 17 MS. CURRY: Object to the form. 18 THE WITNESS: For talc or 19 asbestos? 20 BY MS. O'DELL: 21 Q. Talc. 22 A. No, I disagree with that. I do not 23 believe -- 24 Q. That --</p>
<p style="text-align: right;">Page 283</p> <p>1 THE WITNESS: Page 120 what? 2 I'm sorry, Ms. O'Dell. 3 BY MS. O'DELL: 4 Q. 127. 5 A. Thank you. 6 Q. They say that: "Given the quality 7 of the evidence, the counterargument could be 8 made, namely that the incident rates of ovarian 9 cancer actually is much higher, and that the 10 peritoneal malignant mesothelioma cases are 11 actually misdiagnosed ovarian cancers." 12 Did I read that correctly? 13 A. Yes. 14 Q. And looking at your report, 15 Dr. Saenz, on page 50 -- 57 and 58, does that 16 encompass your review of the most recent studies 17 published on ovarian cancer and asbestos 18 exposure? 19 A. I think that the Dalsgaard study 20 from 2022 is the most comprehensive and certainly 21 the largest study that I have ever seen, and 22 certainly followed study subjects for a much 23 longer time than any of the other prior 24 publications.</p>	<p style="text-align: right;">Page 285</p> <p>1 MS. CURRY: Go ahead, finish. 2 THE WITNESS: I do not believe 3 there is an increased risk of developing 4 ovarian cancer with the perineal 5 application of talc. 6 BY MS. O'DELL: 7 Q. And it's your opinion that there's 8 no data published in the literature regarding 9 genital use of talc and ovarian cancer that 10 demonstrates an increased risk. Is that your 11 testimony? 12 MS. CURRY: Object to the form. 13 THE WITNESS: My opinion is that 14 the literature that has been published 15 is inconsistent. The studies that have 16 found a positive association are 17 inconsistent with the studies that have 18 not found a positive association. The 19 strength of association is weak. There 20 is no biologic plausibility for either 21 the migration or the actual mechanism by 22 which the talc would induce malignant 23 transformation. And there's also no 24 data for migration from the perineum,</p>


<p style="text-align: right;">Page 286</p> <p>1 and there's no biologic gradient data.  2 There is no evidence of a dose-response  3 curve in any of the published  4 literature.  5 BY MS. O'DELL:  6 Q. Based on your -- in your opinion.  7 A. That's what I'm here for is my  8 expert opinion, and that is my expert opinion.  9 Q. Thank you.  10 All right. I think that's my time  11 for general, and I have what I believe to be 15  12 minutes left or so for a few more Converse  13 questions.  14 So, Dr. Saenz, if I could ask you  15 to dig out the Converse report, if you don't  16 mind.  17 A. Yes, ma'am.  18 MS. O'DELL: And, Leslie, would  19 you mind -- or someone tell me exactly  20 how many minutes you think I have.  21 And I'll try to be considerate  22 of your time, Dr. Saenz.  23 BY MS. O'DELL:  24 Q. Dr. Saenz, I hope you can find your</p>	<p style="text-align: right;">Page 288</p> <p>1 mark that Chang 2024 as Exhibit 31.  2 (Exhibit No. 31 was marked for  3 identification.)  4 MS. O'DELL: And I think we have  5 not only the Chang study, but also the  6 tables.  7 MS. BROWN: Yes.  8 MS. O'DELL: And the tables may  9 be separate, and I will mark -- it's S4,  10 Table S4, and I'll go ahead and just  11 mark that as Exhibit 32.  12 (Exhibit No. 32 was marked for  13 identification.)  14 MS. BROWN: So I have Chang S5.  15 MS. O'DELL: Oh, do you? I will  16 put up Chang S4 because that's the table  17 that we need.  18 MS. BROWN: Okay.  19 BY MS. O'DELL:  20 Q. So first, Dr. Saenz, just setting  21 the table for Chang 2024, it was an analysis from  22 the Sister Study. True?  23 A. Correct.  24 Q. And it looked at a myriad of</p>
<p style="text-align: right;">Page 287</p> <p>1 report.  2 A. I have it. It's Exhibit 9,  3 Ms. O'Dell.  4 Q. Thank you.  5 A. You're welcome.  6 Q. I had a genius system that doesn't  7 appear to have worked, but I will get there.  8 A. Always the downfall.  9 Q. I know. I know. I was trying.  10 MS. CURRY: You have 16 minutes  11 left in total.  12 MS. O'DELL: We can do it. All  13 right. I did have a system. I just  14 didn't know what it was.  15 BY MS. O'DELL:  16 Q. So I'm back at Ms. Converse. And  17 Ms. Converse we talked about several times, but  18 just to reset the table, Ms. Converse was a daily  19 user of talc, right?  20 A. Correct.  21 Q. And I want to calculate how  22 Ms. Converse would have been treated to evaluate  23 her risk under the Chang study.  24 MS. O'DELL: You know, so I'll</p>	<p style="text-align: right;">Page 289</p> <p>1 personal care products, everything from not only  2 talc to douching to baby oil, blemish products.  3 It looks at eyeshadow, mascara, hair spray.  4 A. It looked at categories, if you  5 will. So there was a beauty category, a hygiene  6 category, a skin care category, and within each  7 of those categories were various and sundry  8 products.  9 Q. Right. And so talc was included in  10 the hygiene category. Fair?  11 A. Correct.  12 Q. And I would like to take you to  13 Figure 4, which is page 10 of the Chang study.  14 And just let me know when you get  15 there.  16 A. I'm there.  17 Q. And in the middle of the page, it  18 looks at hygiene, and in the single product  19 category looks at everything from bath gel,  20 deodorant, douching, mouthwash, and then talc  21 under arm, talc vaginal, and talc other.  22 And you would agree with me that  23 Ms. Converse's primary use of talc is talc in the  24 vaginal area, correct?</p>

<p style="text-align: right;">Page 290</p> <p>1 A. No, I think it was talc in the 2 perineal area. 3 Q. And you would view that as 4 different as this category that they've 5 identified as talc in the vaginal area? 6 A. I -- I don't ever say that the 7 vagina is the perineum. I don't exactly know why 8 these authors used the word "vagina." I don't 9 think these women were putting talc up into their 10 vagina. I think they were applying it to their 11 perineum, at least that's what the data from the 12 original Sister Study said. So I don't know why 13 these authors call it "vaginal," but it's not the 14 vaginal application of talc. 15 Q. Well, you're not disagreeing with 16 me that these authors when they describe talc, 17 paren, "vaginal," close paren, that they are 18 intending to describe perineal application of 19 talc? 20 A. I think you and I -- 21 MS. CURRY: Object to the form. 22 THE WITNESS: I think you and I 23 are on the same page with that. I don't 24 think that this paper, especially since</p>	<p style="text-align: right;">Page 292</p> <p>1 estimate is just to the right of 1, correct? 2 A. Correct. 3 MS. CURRY: Object to the form. 4 BY MS. O'DELL: 5 Q. And if you -- and of course, they 6 looked at uterine cancer in this study, and we're 7 not talking about uterine cancer. We're only 8 talking about ovarian cancer. Can we agree on 9 that? 10 A. Well, we talked about uterine 11 before, but yes, we're just talking about ovary 12 right now. 13 Q. For this moment -- 14 A. For this moment. 15 Q. -- -- for Chang, that's what we're 16 talking about is ovarian cancer. 17 A. Fair enough. 18 Q. And if you'll turn to page 14, on 19 the left-hand side -- 20 A. I'm there. 21 Q. -- last full paragraph. Do you see 22 that, this study? 23 A. Yes. 24 Q. Go down midway of the paragraph, it</p>
<p style="text-align: right;">Page 291</p> <p>1 it's not new study subjects, correct, 2 it's women from the Sister Study, these 3 were women that were studied placing 4 talc on their genitals, not up into 5 their vagina. 6 BY MS. O'DELL: 7 Q. Well, we were doing great until we 8 got to that. I mean, we don't know that. We 9 know that they are placing it on the perineum, 10 but we don't know if it could have been moved 11 into the vagina through intercourse, moved into 12 the vagina through tampons or any other source, 13 correct? 14 We just know in general this is the 15 category that covers perineal use. We're in 16 agreement, right? 17 A. I think that's fair. 18 Q. And if you look at Table 4, it is 19 an adjusted association between one frequency 20 category increase and the use of personal care 21 products and ovarian cancer. Correct? 22 A. Yes. 23 Q. And in this instance, talc in this 24 single product, one frequency, its dot, or its</p>	<p style="text-align: right;">Page 293</p> <p>1 says: "All of the observed effects of one 2 frequency level increase were modest in 3 magnitude. The impact would be more substantial 4 when comparing the most frequent users with never 5 users. For example, an 8 percent higher hazard 6 of postmenopausal breast cancer for a one 7 frequency level increase in the beauty mixture 8 use could translate into" -- excuse me, "could 9 translate to approximately a 36 percent higher 10 hazard for the most frequent users compared with 11 never users." 12 Did I read that correctly? 13 A. You read that correctly. 14 Q. And what they're saying is that 15 when you look at the increased risk for one 16 frequency, that's only one part of the picture, 17 right? 18 If you have a person that's using 19 multiple times a week, then you actually have to 20 multiply the increased risk in order to know the 21 true rate. True? 22 MS. CURRY: Object to the form. 23 THE WITNESS: They don't show 24 that data. I mean, the frequency that</p>

<p style="text-align: right;">Page 294</p> <p>1 they're looking at is this is a</p> <p>2 basically an ever/never, and they're not</p> <p>3 being -- they're not able to drill down</p> <p>4 to more increased frequency of</p> <p>5 application, and they don't actually</p> <p>6 show that data. I think that that's a</p> <p>7 hypothesis that they're putting forth,</p> <p>8 but they don't actually show that data.</p> <p>9 BY MS. O'DELL:</p> <p>10 Q. Well, do they say it's a</p> <p>11 hypothesis?</p> <p>12 A. They don't have to. It's in their</p> <p>13 Discussion section. It's not in their Results</p> <p>14 section.</p> <p>15 Q. Well, not every statement in a</p> <p>16 Discussion section is an hypothesis, Dr. Saenz.</p> <p>17 They're saying this categorically that the impact</p> <p>18 would be substantially -- would be more</p> <p>19 substantial when comparing the most frequent</p> <p>20 users with never users, and then they give an</p> <p>21 example. Correct?</p> <p>22 MS. CURRY: Object to the form.</p> <p>23 THE WITNESS: They're just</p> <p>24 putting that data forth without actual</p>	<p style="text-align: right;">Page 296</p> <p>1 or four times a week -- do you see what I'm doing</p> <p>2 here?</p> <p>3 MS. CURRY: I'm -- I object.</p> <p>4 I'm not -- I have no idea what you're</p> <p>5 doing here.</p> <p>6 MS. O'DELL: Well, I'm just --</p> <p>7 follow the calculation, if you don't</p> <p>8 mind.</p> <p>9 MS. CURRY: Well, we've been</p> <p>10 going for 12 minutes since you said you</p> <p>11 were turning to Converse, and we haven't</p> <p>12 said the word "Converse" or looked at</p> <p>13 anything about her case --</p> <p>14 MS. O'DELL: I actually have,</p> <p>15 Dawn. I will -- I will -- I've actually</p> <p>16 asked about Converse, but --</p> <p>17 BY MS. O'DELL:</p> <p>18 Q. And so let me be clear, you know,</p> <p>19 the -- let me pull up the Converse tables, and I</p> <p>20 will -- let's do the calculation. I wanted to</p> <p>21 try to explain the calculation as they put it in</p> <p>22 the discussion for this example, and then show</p> <p>23 you what it would be for Converse.</p> <p>24 Do you understand what I'm doing?</p>
<p style="text-align: right;">Page 295</p> <p>1 data from the Results section being able</p> <p>2 to draw that conclusion. So this is</p> <p>3 them putting forth a proposal. It is</p> <p>4 not something that is supported by the</p> <p>5 Results section of their paper.</p> <p>6 BY MS. O'DELL:</p> <p>7 Q. And you are saying that to a</p> <p>8 reasonable degree of scientific certainty?</p> <p>9 A. Yes.</p> <p>10 Q. So, Dr. Saenz, if you took -- and</p> <p>11 I'm going to share my screen, and you should see</p> <p>12 in this a calculator. So I want to --</p> <p>13 MS. CURRY: No, she's not --</p> <p>14 she's sharing her screen.</p> <p>15 BY MS. O'DELL:</p> <p>16 Q. Do you see my -- the calculator I</p> <p>17 have on the screen?</p> <p>18 A. Sure.</p> <p>19 Q. And if the increased risk is</p> <p>20 8 percent, so in other words, based on the data</p> <p>21 we've seen previously, 1 -- excuse me -- 1.08.</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. And you multiply 1.08 times 4 times</p>	<p style="text-align: right;">Page 297</p> <p>1 A. No.</p> <p>2 Q. Okay. Fair enough.</p> <p>3 A. Because I think you're making an</p> <p>4 assumption here that when they say there is a one</p> <p>5 frequency level increase with 8 percent, that</p> <p>6 that somehow correlates to an application once a</p> <p>7 week. And those two don't -- that's not what it</p> <p>8 is. It's not -- you multiply it times four</p> <p>9 because you use it four days a week. That's not</p> <p>10 what it is.</p> <p>11 Q. That's not what I'm doing, by the</p> <p>12 way.</p> <p>13 A. Okay. Well, that's why I'm</p> <p>14 confused.</p> <p>15 Q. Yeah, fair enough. Let's just make</p> <p>16 it Converse because I want to meet Dawn's</p> <p>17 objection.</p> <p>18 This is Table S5. I'm sure -- S4,</p> <p>19 excuse me, association between one frequency</p> <p>20 category increase in use of a single personal</p> <p>21 care product in breast and ovarian and uterine</p> <p>22 cancer.</p> <p>23 Do you see that clearly?</p> <p>24 A. Yes.</p>



<p style="text-align: right;">Page 298</p> <p>1 MS. O'DELL: And I will put this</p> <p>2 in the chat, Leslie, so we can mark the</p> <p>3 table.</p> <p>4 BY MS. O'DELL:</p> <p>5 Q. But it's Table S4. And this is --</p> <p>6 I'm in the ovarian cancer column. Do you see</p> <p>7 that?</p> <p>8 A. Yes.</p> <p>9 Q. And I tried to highlight it so it</p> <p>10 would be clear to see. And so I will scroll down</p> <p>11 to the hygiene category, and you see I've</p> <p>12 highlighted "talc vaginal," and it's the -- fully</p> <p>13 adjusted as a ratio is 1.04.</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And so going back to my example --</p> <p>17 and I'll just stop using the one that's in the</p> <p>18 study, and just clear this out so it's</p> <p>19 essentially zero -- and let's calculate</p> <p>20 Ms. Converse and what it would be -- forgive me,</p> <p>21 I just need to open this again -- what it would</p> <p>22 be under the scenario 1.04.</p> <p>23 Do you see that? 1.04 is what the</p> <p>24 hazard ratio or the adjusted ratio was -- fully</p>	<p style="text-align: right;">Page 300</p> <p>1 doesn't say that.</p> <p>2 Q. Well, what they say in their study,</p> <p>3 and you have it there in front of you, they said:</p> <p>4 "The impact" -- they're talking -- "although the</p> <p>5 observed effects of one frequency level increase</p> <p>6 were modest in magnitude," that would be true of</p> <p>7 talc, "the impact would be more substantial when</p> <p>8 comparing the most frequent users with never</p> <p>9 users."</p> <p>10 That's what we read earlier,</p> <p>11 correct?</p> <p>12 A. That's a sentence that they put</p> <p>13 forth, but they don't show the data for that.</p> <p>14 Q. They go forward and they do show</p> <p>15 data.</p> <p>16 A. No --</p> <p>17 Q. They say, for example -- let me</p> <p>18 just finish -- "An 8 percent higher hazard of</p> <p>19 postmenopausal breast cancer for one frequency</p> <p>20 level increase in the beauty mixture use could</p> <p>21 translate to approximately 36 percent higher</p> <p>22 hazard for the most frequent users compared with</p> <p>23 never users."</p> <p>24 Did I read that correctly?</p>
<p style="text-align: right;">Page 299</p> <p>1 adjusted hazard ratio was for talc in the vaginal</p> <p>2 area. Correct?</p> <p>3 MS. CURRY: Object to the form.</p> <p>4 Are you ignoring the statistical</p> <p>5 significance?</p> <p>6 MS. O'DELL: I'm not.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. I'm saying that's the hazard ratio</p> <p>9 that they reported in this table. True?</p> <p>10 MS. CURRY: Object to the form.</p> <p>11 BY MS. O'DELL:</p> <p>12 Q. This 1.04.</p> <p>13 A. For talc, correct.</p> <p>14 Q. And so if you took -- if she's a</p> <p>15 seven-day-a-week user, which is what she is,</p> <p>16 right? Ms. Converse is a seven-day-a-week user,</p> <p>17 daily user?</p> <p>18 A. Correct.</p> <p>19 Q. And she's not a one-time frequent</p> <p>20 user. She's a seven-day user, true?</p> <p>21 A. This isn't a one-time frequent</p> <p>22 user. That's where you're losing me. So I'm not</p> <p>23 quite sure how you're taking that phrase and</p> <p>24 translating it into the number of days. It</p>	<p style="text-align: right;">Page 301</p> <p>1 A. You read it correctly, but that's a</p> <p>2 proposition. They say "could." That's not</p> <p>3 actual data.</p> <p>4 MS. CURRY: And we're actually</p> <p>5 at -- we're over the time allotted for</p> <p>6 seven hours at this point.</p> <p>7 MS. O'DELL: Okay. So I have no</p> <p>8 more time, that's seven hours?</p> <p>9 MS. CURRY: It's seven hours.</p> <p>10 MS. BROWN: Leigh, can you put</p> <p>11 the last exhibit in the chat so we can</p> <p>12 have it --</p> <p>13 MS. O'DELL: I would be happy</p> <p>14 to. It's Table S4, but it's all in one</p> <p>15 Excel spreadsheet.</p> <p>16 All right.</p> <p>17 MS. CURRY: I think -- hold on,</p> <p>18 I have one question just so that the</p> <p>19 exhibit is clear. On my tables for</p> <p>20 Chang, Table S4 that's at the top that</p> <p>21 you're using, on the bottom it's</p> <p>22 actually labeled as Table S5. So I just</p> <p>23 want to make sure that when you mark it,</p> <p>24 if you went to the tab, it would be</p>

<p style="text-align: right;">Page 302</p> <p>1 Table S5, but in reality at the top, 2 it's Table S4 is the one that we've been 3 using, just so the right one is marked 4 as an exhibit. 5 THE WITNESS: Maybe you do have 6 it, Paula. So Paula might have it. 7 MS. CURRY: Let me see it and 8 you might not have to put it in there. 9 MS. O'DELL: I think -- well, 10 let's see what you have, Paula. 11 MS. CURRY: No, this is the 12 wrong one. 13 MS. O'DELL: It's mislabeled. 14 Actually -- 15 MS. CURRY: Yeah. 16 MS. O'DELL: -- what I had 17 pulled down from the paper itself is the 18 actual spreadsheet I showed. So I think 19 they actually mislabeled it in the 20 published version or the online version 21 the tables at the bottom. 22 So with your agreement, Dawn, I 23 will make a PDF of Table S4 so it's 24 clear, and I will e-mail it to -- to --</p>	<p style="text-align: right;">Page 304</p> <p>1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER 2 The undersigned Certified Shorthand 3 Reporter does hereby certify: 4 That the foregoing proceeding was 5 taken before me at the place and time therein 6 set forth, at which time the witness was duly 7 sworn; That the testimony of the witness and 8 all objections made at the time of the 9 examination were recorded stenographically by 10 me and were thereafter transcribed, said 11 transcript being a true and correct copy of my 12 shorthand notes thereof; That the dismantling 13 of the original transcript will void the 14 reporter's certificate. 15 In witness thereof, I have 16 subscribed my name this date: July 2, 2024. 17  18 19 LESLIE A. TODD, CSR, RPR 20 Certificate No. 5129 21 22 23 (The foregoing certification of 24 this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)</p>
<p style="text-align: right;">Page 303</p> <p>1 maybe, Leslie, you can send me your 2 e-mail, and I will e-mail everybody so 3 you have it, and that will be what is 4 marked as Exhibit 32. 5 Do we have agreement that that 6 works? 7 MS. CURRY: That works. Thank 8 you. 9 MS. O'DELL: Okay. Great. 10 Dr. Saenz, thank you for today. 11 THE WITNESS: Thank you. 12 MS. O'DELL: And hope everybody 13 has a good evening. We will see you all 14 tomorrow. 15 THE WITNESS: Nine o'clock 16 tomorrow, Leigh? I'm just confirming. 17 MS. CURRY: Yes, that's right. 18 (Whereupon, the deposition of 19 CHERYL C. SAENZ, M.D. was 20 adjourned at 5:30 p.m.) 21 22 23 24</p>	<p style="text-align: right;">Page 305</p> <p>1 INSTRUCTIONS TO WITNESS 2 Please read your deposition over 3 carefully and make any necessary corrections. 4 You should state the reason in the appropriate 5 space on the errata sheet for any corrections 6 that are made. 7 After doing so, please sign the 8 errata sheet and date it. 9 You are signing same subject to the 10 changes you have noted on the errata sheet, 11 which will be attached to your deposition. It 12 is imperative that you return the original 13 errata sheet to the deposing attorney within 14 thirty (30) days of receipt of the deposition 15 transcript by you. If you fail to do so, the 16 deposition transcript may be deemed to be 17 accurate and may be used in court. 18 19 20 21 22 23 24</p>

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20 REASON: \_\_\_\_\_

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22 REASON: \_\_\_\_\_

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24 REASON: \_\_\_\_\_

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1 ACKNOWLEDGMENT OF DEPONENT

2 I, \_\_\_\_\_, do hereby

3 certify that I have read the foregoing pages,

4 and that the same is a correct transcription

5 of the answers given by me to the questions

6 therein propounded, except for the corrections

7 or changes in form or substance, if any, noted

8 in the attached Errata Sheet.

9

10 Dated: \_\_\_\_\_

11

12 \_\_\_\_\_

13 CHERYL C. SAENZ, M.D.

14

15 Subscribed and sworn to

16 before me this

17 \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

18 My commission expires: \_\_\_\_\_

19 \_\_\_\_\_

20 Notary Public

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22

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.



VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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